Supreme Court, U.S.
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No. 99 337

THE SUPREME COURT OF THE UNITED STATES

JANIS SOWERBY, as Personal Representative of the Estate of SCOTT MICHAEL HINKLEY, deceased, KAREN BOULAHANIS, GEORGE BOULAHANIS, individually and as next friend of BRIDGIT BOULAHANIS, a minor, KARA BOULAHANIS, a minor and BRIAN BOULAHANIS, a minor

Petitioners

v.

PREVO'S FAMILY MARKET, INC., a Michigan Corporation; I.B.P., INC., a Foreign Corporation and SPARTAN STORES, INC., a Michigan Corporation, Jointly and Severally,

---

On Petition For Writ Of Certiorari To The Michigan Court of Appeals

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

I. WHETHER THE MICHIGAN COURT OF APPEALS DECISION HAS UNINTENDED EFFECT OF JEAOPARDIZING THE HEALTH AND SAFETY OF MICHIGAN CONSUMERS BY IMMUNIZING MEAT VENDORS FROM ALL LIABILITY EVEN WHEN THEY KNOWINGLY DISTRIBUTE FOOD CONTAMINATED WITH A NEWLY EMERGED OR MUTATED PATHOGEN?

II. WHETHER THE MICHIGAN COURT OF APPEALS ERRED IN FINDING FEDERAL PREEMPTION OF PLAINTIFF-APPELLANTS/APPELLANTS STATE LAW TORT CLAIMS?

III. WHETHER THE MICHIGAN COURT OF APPEALS ERRED IN APPLYING RYAN V BRUNSWICK, 454 MICH 20, 557 NW2D 541 (1997) TO THIS CASE?

IV. WHETHER IT IS THE OFFICIAL OPINION OF TH E UNITED STATES GOVERNMENT THAT MICHIGAN WRONGLY FOUND IMPLIED PREEMPTION IN RYAN V. BRUNSWICK?

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OPINION BELOW

The opinion of the Michigan Supreme Court is reported at 591 N.W. 2d 38 (1999) and is attached as Appendix F. The opinion of the Michigan Court of Appeals is reported at 230 Mich. App. 131, 583 N.W. 2d 509 (1998). It is attached as Appendix A. The opinion of the Circuit Court for the county of Mason has not been reported, it is attached to this pleading, and designated as Appendix B.

JURISDICTION

Petitioners' case in the circuit court for the county of Mason was dismissed on summary disposition on June 25, 1996. The court of appeals of the state of Michigan affirmed the summary disposition in an opinion dated June 2, 1998. The Michigan Supreme Court denied petitioners' leave to appeal the court of appeals decision in an order dated March 30, 1999. The jurisdiction of this court is invoked under 28 U.S.C. §1257(a)

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

MCLA § 289.586

Sec. 6. Any product within the purview of this act shall be considered adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health or if it contains any diseased, contaminated, filthy, or decomposed substance, or if it is manufactured in whole or in part from a diseased, contaminated, filthy, or decomposed substance, if it is the product of an animal which has died otherwise than by slaughter, or if it has been produced, prepared, packed, or held under unsanitary conditions which may have contaminated the product.

MCLA § 289.590

Sec. 10. (1) A person who, by himself or herself, or by the person's employee, servant, or agent or as an employee, servant, or agent of another, does any of the following is guilty of a misdemeanor punishable by a fine of not less than $100.00 or more than $500.00 and the costs of prosecution, or by imprisonment for not more than 90 days, or both :

(a) By means of labeling, seal, placard, newspaper, window banner, handbill, bulletin, bulletin board, radio, television, or otherwise, publicly advertises falsely with reference to the composition of products within the scope of this act manufactured, sold, or offered for sale by that person.

(b) Manufactures, sells, offers for sale, exposes for sale, or has in his or her possession with intent to sell a comminuted meat product that is improperly branded or mislabeled.

(c) Manufactures, sells, offers for sale, exposes for sale, or has in his or her possession with intent to sell a comminuted meat defined in section 2 > [FN1] containing excess water or fat.

(2) The director, upon belief that a person or a person's agent or employee or as servant or agent of another is in violation of subsection (1)(a), (b), or (c), may enter into a consent agreement for the assessment of a civil fine of not less than $100.00 or more than $500.00 plus actual costs of investigation for those violations instead of criminal prosecution.

(3) If a person alleged to have violated subsection (1)(a), (b), or (c) does not enter into a written consent agreement as described in subsection (2), the director shall either hold a hearing conducted pursuant to the administrative procedures act of 1969, Act No. 306 of the Public Acts of 1969, being > sections 24.201 to > 24.328 of the Michigan Compiled Laws, or initiate a criminal prosecution.

(4) The director shall advise the attorney general of the failure of any person to pay an administrative fine imposed under this section. The attorney general shall bring a civil action in a court of competent jurisdiction to
recover the fine.

(5) Civil penalties collected shall be paid to the state treasury and credited to the department for the enforcement of this act.

(6) A person who, by himself or herself or by the person's employee, servant, or agent, or as the employee, servant, or agent of another, manufactures, sells, offers for sale, exposes for sale, or has in his or her possession with intent to sell an adulterated comminuted meat or a meat product containing a substance either specifically prohibited or not specifically allowed or who otherwise does not meet the standards set forth in this act other than excess water or fat is guilty of a misdemeanor punishable by a fine of not less than $200.00 or more than $2,000.00 and the costs of prosecution, or by imprisonment for not more than 90 days, or both.

(7) If a violation results in a criminal conviction under this act, the court may assess against the defendant the costs of investigation, including, but not limited to, the costs of laboratory analysis. Costs assessed and recovered under this subsection shall be paid to the state treasury and credited to the department for the enforcement of this act.

9 CFR § 318.10(a)(1)

Prescribed treatment of pork and products containing pork to destroy trichinae.

(a)(1) All forms of fresh pork, including fresh unsmoked sausage containing pork muscle tissue, and pork such as bacon and jowls, other than those covered by paragraph (b) of this section, are classed as products that are customarily well cooked in the home or elsewhere before being served to the consumer. Therefore, the treatment of such products for the destruction of trichinae is
not required.

21 USC § 601(m)(1)

The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

21 USC § 601(m)(3)

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

21 USC § 602

Congressional statement of findings

Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign

commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses
to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

21 USC § 661(a)

Federal and State cooperation

(a) Congressional statement of policy

It is the policy of the Congress to protect the consuming public from meat and meat food products that are adulterated or misbranded and to assist in efforts by State and other Government agencies to accomplish this objective. In furtherance of this policy--

21 USC § 678

Non-Federal jurisdiction of federally regulated matters;

prohibition of additional or different requirements for establishments with inspection services and as to marking, labeling, packaging, and ingredients; recordkeeping and related requirements; concurrent jurisdiction over distribution for human food purposes of adulterated or misbranded and imported articles; other matters

Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are in addition to, or different than those made under this chapter may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 642 of this title, if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this chapter, but any State or Territory or the District of Columbia may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This chapter shall not preclude any State or Territory or the District of Columbia from making requirement or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

STATEMENT OF THE CASE

This is a product liability claim arising from the sale of ground round contaminated with E. Coli 0157:H7 resulting in the death of a 3 year old and serious injury to three other children.

In their Second Amended Complaint (filed on 1-8-96; Order Granting Leave entered: 2-6-96), Plaintiffs Boulahanis allege that Defendant, I.B.P., Inc. is a manufacturer/slaughterhouse, and a producer of beef products, including certain "ground round" which the Plaintiffs purchased on or about July 15, 1993 (Second Amended Complaint, p. 2, para. 3, 7). Plaintiffs purchased the meat at Prevo's Family Market, also named as a Defendant. Id, para. 2, 7. On July 15 and 16 of 1993, Plaintiffs prepared, cooked and consumed the meat, which had been supplied to the store by Defendant, Spartan Stores, a wholesaler or distributor of food. Id, para. 4, 8. Unknown to Plaintiffs, the meat was unwholesome, adulterated and defective because it was contaminated with deadly Escherichia Coli 0157:H7 (hereinafter "E. Coli"), a bacteria found in the colon of beef cattle which causes deadly hemolytic uremic syndrome (HUS). Id, para. 9. After Plaintiffs consumed the meat, the children, Kara and Brian, suffered HUS,

while Brian suffered profound neuropsychological problems. Bridgit Boulahanis and her mother suffered Pre-HUS.

Plaintiffs allege that the Defendants knew or should have known of the danger to consumers presented by E. Coli contaminated meats, and should have taken appropriate measures to prevent its sale and warn consumers of the dangers posed thereby. Id, para. 11. Plaintiffs further allege that the Defendants had violated MCLA 289.586 by selling adulterated meat, and that Plaintiffs were within the class of persons intended to be protected by that statute. Id, para. 12. Plaintiffs assign liability to each of the Defendants under breach of implied warranty and negligence theories (Second Amended Complaint, pp. 3-9).

Plaintiff, Janis Sowerby is the personal representative of the Estate of Scott M. Hinkley, who died at age three on July 30, 1993, from HUS caused by the deadly E. Coli 0157:H7 bacteria. The ground round was purchased from the same Defendants.

The procedural history for both circuit court cases are the same and the Circuit Court's Order of Summary Disposition has a combined caption (Opinion and Order dated June 25, 1996).

It was at this stage of the proceedings that the federal question was first raised. All three Defendants raised federal preemption as an affirmative defense (Defendant Prevo's Second

Amended Answer and Affirmative Defenses, p. 6; I.B.P.'s Answer to Second Amended Complaint, p. 7; Spartan's Answer to Second Amended Complaint, p. 6)

Defendant Prevo's moved for summary disposition (Motion filed on 2-29-96), asserting that Plaintiffs' claims, in their entirety, are preempted by the Federal Meat Inspection Act, 21 USC Sec. 601, et seq. According to Defendant, E. Coli had not been deemed by the Federal Government to be an "adulterant" of meat, within the meaning of the Federal statute, in July of 1993. Id, p. 2, para. 4. Defendant hinged its preemption defense upon 21 USC Sec. 678 (quoted at p. 10 infra), and upon this Court's decision in the pork/trichinosis case of Kircos v Holiday Food Cent[illegible], 191 Mich App 82 (1991), lv den 440 Mich 877 (1992).

The other two Defendants joined in the Motion for Summary Disposition (Spartan's "Joinder" filed on 3-13-96; I.B.P.'s Joinder filed on 4-8-96). Plaintiffs filed an Answer to the Motion for Summary Disposition, and the Brief (filed on 4-15-96), as well as a "Rebuttal" to a "Reply Brief" filed by Defendants ("Rebuttal" filed on 5-13-96).

The Circuit Court held a hearing on the Motion for Summary Disposition, taking the matter under advisement (see, TR, 4-22-96). On June 25, 1996, the Circuit Court Judge issued his Opinion and

Order granting the Motion for Summary Disposition. The Circuit Judge first concluded that the Federal Meat Inspection Act "preempts any requirement that Defendants had a responsibility to provide warning labels on the ground beef different or in addition to that required by the Wholesome Meat Act." Id, p. 3; rely upon, 21 USC Sec. 678; Kircos, supra, 191 Mich App 82. As to the remainder of the Plaintiffs claims, the Circuit Judge stated:

> Further, this Court is bound by the Kircos ruling that there can be no recovery under State tort law. Because Federal law and regulation had not in 1993 determined Escherichia Coli to be an adulterant, food retailers and meat packers were not required to test for or treat meat in 1993 for Escherichia Coli contamination. Plaintiffs make a well reasoned argument that Defendants should have known better and/or tested on their own because the industry knew of such dangers whereas the general public did not. However, as noted above, the Kircos case specifically states that this subject area is preempted by Federal law and regulation and that a tort claim cannot be utilized to seek recovery. Plaintiffs' present claims rest in negligence and implied warranty which are both tort actions.

Opinion and Order Regarding Defendants' Motion for Summary Disposition, pp. 3-4).

On July 8, 1996, Plaintiffs moved for rehearing and reconsideration, citing This Honorable Court's Federal preemption decision in Medtronic, Inc. v Lohr, 518 US 470; 116 SCt 2240; 135 Led 2d 700 (1996), which had been released the day after the Circuit Court's grant of Summary Disposition (6-26-96). The Circuit

Court denied the Motion (Order entered on 8-12-96). In an effort to distinguish Medtronic, the Circuit Judge stated:

> In Medtronic, the pacemaker involved had been marketed at a time when Class 3 medical devices were subject to Federal approval; however, the applicable status recognized that some devices would be grandfathered without extensive testing if their design was substantially similar to a re-existing device which had been marketed prior to the effective date of the new Federal statute. The Medtronic Court observed that although a device was thus allowed to be marketed, its usage did not mean that it had escaped common law claims for negligent design or manufacture or labeling. Further, the FDA had sent a letter to Medtronic observing that the Section 510(k) process and the 4011 "substantial equivalent" language did not constitute FDA approval of its pacemaker. Where the pacemaker had been marketed under the "substantial equivalence" language, the United States Supreme Court found that the device continued to be subject to common law tort challenges.
>
> The facts in Medtronic are substantially dissimilar to our present case. Although negligent design and breach of implied warranty may overlap, our present case deals with meat inspection and labeling situations. It is not a tort action for negligent design nor does our case involve a product which was marketed under a "substantial equivalent" provision. Kircos remains Michigan's controlling law.

Plaintiffs' motion for rehearing and reconsideration is DENIED.

(Order Regarding Plaintiffs' Motion for Rehearing and Reconsideration; 8-12-96, p. 2).

Because Plaintiffs believe that Defendants and the Circuit Judge are mistaken in their reliance upon Kircos, supra, and in their effort to distinguish the controlling Federal preemption jurisprudence

of This Honorable Court, they timely filed their Claim of Appeal of Right on August 21, 1996.

The Court of Appeals consolidated the cases of Karen Boulahanis v Prevos Family Market, Inc, et al, Docket No. 197343 and Janis Sowerby v Prevo's Family Market, Inc. et al., Docket No. 197344.

On June 2, 1998, the Court of Appeals released its Opinion for Publication affirming the granting of summary disposition by the trial court. However, the trial court premised its Judgment on Kircos v Holiday Food Center, 191 Mich App 82 (1991) lv den 440 Mich 87 (1992).

The Court of Appeals affirmed the trial court's Judgment but its Opinion never mentioned Kircos supra but relied completely on Ryan v Brunswick Corp., 454 Mich 20, 557 NW2d 541 (1997). On March 30, 1999, the Supreme Court of the state of Michigan denied the petitioner's application for leave to appeal from the June 2, 1998 decision of the Court of Appeals. Plaintiffs are convinced the Court of Appeals erred in affirming the decision of the circuit court.

ARGUMENT

I. **THE APPEAL COURT'S ERRONEOUS DECISION JEOPARDIZES THE SAFETY OF MICHIGAN CITIZENS BECAUSE IT GIVES CARTE BLANCHE TORT IMMUNITY TO FOOD PROCESSORS AND**

SELLERS WHO KNOWINGLY SELL MEAT CONTAINING NEW PATHOGENS (MICROORGANISMS PRODUCING DISEASE OR DEATH IN HUMANS) TO MICHIGAN CONSUMERS.

This case involves issues of compelling public interest and involves legal principles of preemption and a state's right to protect the health and safety of its own citizens food sources.

The Appellate Court's adverse decision was clearly erroneous and has caused a material injustice by depriving a dead 3 year old and three other seriously injured children any tort remedy whatsoever against the persons who sold them ground round contaminated with the deadly E. Coli 0157:H7 bacteria. Moreover, the Appellate Court's erroneous decision has jeopardized the health and safety of all Michigan citizens because it grants tort immunity to food producers who **knowingly** sell food contaminated with a **new** deadly pathogen.

New pathogens are emerging almost daily. This Honorable Court will recall the fear and deaths that occurred in the United Kingdom when mad cow disease emerged. It is believed that mad cow disease is caused by a type of virus that was newly developed as a result of feeding ground bone meal to sheep to accelerate their growth. Sheep are herbivores and do not normally eat other animals except in today's agribusiness.

The danger of the instant appellate court ruling is that it can be interpreted to mean that unless the USDA lists a specific pathogenic organism as an "adulterant", there is no need for a meat producer to worry about selling meat contaminated with it because the meat producer will have tort immunity! Diseases are emerging in food so rapidly that it is impossible for the USDA to list every possible pathogen in its regulations, particularly as some of the pathogens we may face in the near future do not yet exist! It is enough for the USDA and the State of Michigan to ban adulterants from food and simply to define them, as any substance that is deleterious or poisonous and can cause injury to humans. Nature does not wait for bureaucratic procedure.

II. "THERE HAVE BEEN E. COLI 0157:H7 OUTBREAKS BEFORE 1994 AND AFTER, THROUGHOUT THE UNITED STATES AND THIS MICHIGAN APPEALS COURT IS THE ONLY COURT IN THE UNITED STATES THAT HAS DENIED ITS OWN CITIZENS RECOURSE TO A STATE TORT CLAIM ON THE GROUNDS OF FEDERAL PREEMPTION. ARE ALL OF THE OTHER STATE COURTS WRONG?

These Plaintiffs are the **only** victims of E. Coli 0157:H7 poisoning in the United States to be denied any tort remedy. Thousands of people have died or been sickened after consuming hamburger contaminated with E. Coli 0157:H7. In California, Ohio,

the Pacific Northwest states (the notorious Jack in the Box hamburger outbreak) and other states before 1994 and after 1994 and plaintiffs have all successfully pursued their state remedies with no state court finding federal preemption. Only Michigan finds a product liability suits by its injured citizens are preempted by federal law. Its seems improbable that 49 other state trial and high courts are wrong on the issue of federal preemption but our appellate panel's harsh judgment is correct. According to the Michigan Court of Appeals' ruling, Scotty's mom and dad would be compensated had he been poisoned in 1994 or if he was poisoned in Ohio or any other state but Michigan.

Under Article VI, Clause 2 of the United States Constitution, the "Constitution and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any state to the contrary notwithstanding." Under this "Supremacy" clause, Congress may preempt state law. Louisiana Public Service Commission v. Federal Communications Commission, 476 US 355, 368; 106 SCt 1890; 90 LEd 2d 369 (1986). Nevertheless, the states are free to impose additional requirements upon private conduct or actors, so long as

they do not conflict with Federal purposes or directly conflict with Federal enactments. California Federal Savings and Loan Ass'n v. Guerra, 479 US 272; 107 SCt 683; 93 LEd 2d 613, 626 (1987).

In determining whether a Federal statute preempts a Plaintiff's common law or other state law claims, the basic inquiry is whether "Congress intended that Federal regulations supersede state law." Louisiana Public Service Commission, supra, 476 US 355, 369. The Courts begin "with the assumption that the historic police powers of the states were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Rice v. Santa Fe Elevator Corp., 331 US 218, 230; 67 SCt 1146; 91 LEd 1447 (1947). "It will not be presumed that a Federal statute was intended to supersede the exercise of power by the State unless there is a clear manifestation of intention to do so." New York Department of Social Services v. Dublino, 413 US 405, 413; 93 SCt 2507; 37 LEd 2d 688 (1973). Historically, preemption has been the result where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, or where compliance with both Federal and State regulations is a physical impossibility. Florida Lime and Avocado Growers v. Paul, 373 US 132; 83 SCt 1210; 10 LEd 2d 248 (1963); Roysdon v. R.J. Reynolds Tobacco, 849 F2d 230, 33-34 (CA6, 1988). Where there is a specific preemption provision in a

Federal statute, there is no need to consider whether preemption should be implied from the law or from Federal regulations. The question at that point is the proper interpretation of the express preemption provision. Cipollone v. Liggett Group, Inc., 505 US 504; 112 SCt 2608; 120 LEd 2d 407, 423 (1992). As noted in Cipollone (id):

> When Congress has considered the issue of preemption and has included in the enacted legislation a provision explicitly addressing that issue, and when the provision provides a "reliable indicium of congressional intent with respect to state authority," * * * "there is no need to infer congressional intent to preempt state law from the substantive provisions" of the legislation (citations omitted).

Additional precedent dictates that the presumption against preemption be particularly strong where no Federal remedy exists to replace the precluded state law tort recovery. Silkwood v. Kerr-McGee Corp., 464 US 238, 251; 104 SCt 615; 78 LEd 2d 443 (1984). "Moreover, it is the burden of the party arguing in favor of preemption to show that Congress intended to preempt state law." Walker v. Johnson & Johnson, 217 Mich App 705, 715 (1996); citing, Silkwood, 464 US 238, 255. In one such decision, the This Honorable Court found it "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." Silkwood, 464 US at p.251. Preemption where no Federal remedy exists is presumptively avoided, because it might leave the

Plaintiff "without recourse" and grant the Defendant "immunity from liability for their tortious conduct." United Construction Workers v. LaBurnum Corp., 347 US 656, 663-64; 74 SCt 833; 98 LEd 2d 1025 (1954).

Finally, it must be presumed that Congress did not intend to preempt areas of traditional state regulation. Metropolitan Life Insurance Co. v. Massachusetts, 471 US 724; 105 SCt 2380; 85 LEd 2d 728, 740-41 (1985). This Honorable Court very recently noted that "throughout our history the several states have exercised their police powers to protect the health and safety of their citizens," and that because these are "primarily, and historically,...matter[s] of local concern...the 'States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort and quiet of all persons.'" Medtronic, Inc. v. Lohr, 518 US 470; 116 SCt 2240; 135 LEd 2d 700, 709 (1996); quoting, Metropolitan Life, 471 US 724, 756.

Defendants urge, and the Circuit Court ruled, that Plaintiffs' claims, arising from their consumption of E. Coli-infected beef, are preempted by 21 USC Sec. 678, the express preemption section of the Federal Meat Inspection Act, which provides in pertinent part:

> Requirements within the scope of this Chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this Chapter, which are in addition to, or

> different from those made under this Chapter may not be imposed by any State or Territory or the District of Columbia * * *. Marking, Labeling, packaging or ingredient requirements in addition to, or different than, those made under this Chapter may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under subchapter I of this Chapter, but any Estate or Territory or the District of Columbia may, consistent with the requirements under this Chapter, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said subchapter I, for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment... This Chapter shall not preclude any State or Territory or the District of Columbia from making requirements or taking other action, consistent with this Chapter, with respect to any other matters regulated under this Chapter.

What did Congress expressly preclude, insofar as state law is concerned? It precluded state law "requirements" concerning meat regulated by the Federal Meat Inspection Act, "which are in addition to, or different from those made" under that statute. Id. Congress forbade "marking, labeling, packaging, or ingredient requirements in addition to, or different than," those "made under" the Federal meat inspection law. Id. On the other hand, Congress expressly provided that the states may regulate federally regulated meat "for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated..." Id. Thus, where the condition of which the Plaintiffs complain, and as to which the Plaintiffs assert

common law theories of recovery, is not federally regulated, and is the subject to no Federal requirements, either directly under the statute or by regulation, state law claims should be allowed.

It would be a monstrous conclusion that Plaintiffs cannot bring their claims, because they were unfortunate enough to purchase the meat before the Federal government became involved with the E. Coli situation, but that they could bring such claims afterward, because those claims would be consistent with Federal law! Yet that is the very result of the Circuit Court's erroneous preemption analysis.

The Federal government did (in 1994) conclude that E. Coli was an adulterant, and issued an interpretive ruling, or announcement, to that effect. "Prior to this announcement, the USDA had treated pathogen-contaminated meat as unadulterated under the [Federal Meat Inspection Act]." Texas Food Industry Ass'n v. Espy, 870 F Supp 143, 145 (WD Tex. 1994).[1] Indeed, it was in Espy that the Court rejected the meat producers' argument that the Federal government should not regulate the subject matter. The District Court concluded that the Federal government had acted properly, in both a procedural and substantive sense, by instituting its anti-E. Coli

[1] As noted in Espy, "Pathogens are food borne bacteria such as E. Coli and Salmonella." 870 F Supp at 145, fn.2.

program, and by ruling that E. Coli is an "adulterant" under the Federal Meat Inspection Act. 870 F Supp at 146-148.

In this case, the Federal government has, since Plaintiffs purchased and consumed the ground beef, determined that meat with E. Coli present within it is adulterated. Plaintiffs' claims, and Michigan law, are therefore consistent with Federal law. That the Federal government had not yet determined, at the time of Plaintiffs' consumption of the meat, that the meat was adulterated for having E. Coli within it does not mean that it was not, in fact and in law, adulterated prior to that time.

Under MCLA 289.586:

> Any product within the purview of this Act shall be considered adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health or if it contains any diseased, contaminated, filthy, or decomposed substance, or if it is manufactured in whole or in part from a diseased, contaminated, filthy, or decomposed substance, if it is the product of an animal which has died otherwise than by slaughter, or if it has been produced, prepared, packed, or held under unsanitary conditions which may have contaminated the product.

Under Federal law, similarly, a meat product is "adulterated" if it "bears or contains any poisonous or deleterious substance which may render it injurious to health..." 21 USC Sec. 601(m)(1). In addition, meat is "adulterated" if "it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason

unsound, unhealthful, unwholesome, or otherwise unfit for human food." 21 USC Sec. 601(m)(3). The State and Federal definitions are quite similar.

The express preemption provision, the controlling section for purposes of this Court's preemption analysis, Cipollone, supra, specifically allows the states to "exercise concurrent jurisdiction with the Secretary over articles required to be inspected under [the Act] for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated..." 21 USC Sec. 678. State regulation of items which have not yet been regulated by Congress, in any fashion whatsoever, or even by the Federal Meat Inspection Agency, is consistent with the congressional purpose, which is the protection of the public health. As Congress noted in its "Statement of Findings" under the Federal Meat Inspection Act (21 USC Sec. 602):

> Meat and meat food products are an important source of the nation's total supply of food. They are consumed throughout the nation and the major portion thereof moved in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to

livestock producers and processors of meat and meat food products, as well as injury to consumers...

This is not a case in which allowance of the state regulation or common law assertion would be at direct odds with a specific congressional enactment in the meat regulation field, or with a specific regulation issued under the Federal Meat Inspection Act.[2]

Certainly, compliance with the Federal statute and the jury's finding of liability in this case would not leave the Defendants between a "rock and a hard place," nor would it demonstrate that compliance with both state, common law standards and the Federal statute and regulations would be a physical impossibility. Florida Lime and Avocado Growers, 373 US 132, 142-43; 10 LEd 2d 248, 257. There was no Federal regulation or regulatory action by the Federal Meat Inspection Agency prior to 1994. The Defendants were free to treat E. Coli-infected meat in a safe fashion, according to common law,

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[2] Plaintiffs have referred to the Michigan anti-adulteration of meat law, MCLA 289.586, only as a source for a reasonable jury's conclusion that the Defendants acted in a negligent fashion. Violation of a statute creates a rebuttable presumption of negligence, under Michigan law. Klanseck v. Anderson Sales & Service, 426 Mich 78, 86 (1986); Zeni v. Anderson, 397 Mich 117, 128-29 (1976). Plaintiffs' claims are common law claims, with Plaintiff citing the statute only as a legal aid to the assertion of their common law theories.

negligence and implied warranty, standards. Under Michigan's common law, the placement of a product "on the market creates the requisite relationship between a manufacturer, wholesaler and retailer and persons affected by use of the product giving rise to a legal obligation or duty to the persons so affected." Moning v. Alfono, 400 Mich 425, 439 (1977). A seller is liable, under Michigan's common law, depending on the level of its awareness of the risk of harm, for either negligence or breach of implied warranty in tort, whether the product was manufactured by that supplier itself or by another. Kosters v. 7-UP Company, 595 F2d 347, 351 (CA6, 1979) (Michigan citations omitted). In 1994, Plaintiffs' theory become consistent with affirmative Federal regulation of E. Coli-tainted meat. That Plaintiffs' claims are consistent with affirmative Federal regulatory action taken in 1994 should not lead to the weird finding or legal conclusion that their claims, arising a year earlier, are somehow preempted by the Federal government's previous inaction. Prior to 1994, and in the absence of Federal regulation or statute to the contrary, the Defendants had a common law duty, under Michigan law, to place into the stream of commerce meat which was reasonably fit for human consumption. See, Gaulthier v. Mayo, 77 Mich App 513, 515 (1977); MCLA 289.586, supra. There is no inevitable collision between the two schemes, Michigan's common law, and the Federal

Meat Inspection Act and regulation. Guerra, supra, 479 US 272, 107; 93 LEd 2d 613, 630. Federal silence, pre-1994, and the absence of interpretive rules by the Federal agency with regard to E. Coli, cannot lead to a finding of preemption. If preemption should "not be inferred...simply because the agency's regulations are comprehensive, R.J. Reynolds Tobacco v. Durham County, 479 US 130; 107 SCt 499; 93 LEd 2d 449, 467 (1986), an absence of preemption should even more especially be the proper conclusion where the agency's regulations are not comprehensive. As This Honorable Court has noted with respect to the preemptive effect of regulations (or lack of same):

> We are even more reluctant to infer preemption from the comprehensiveness of regulations then from the comprehensiveness of statutes. As a result of their specialized functions, agencies normally deal with problems in far more detail than does Congress. To infer preemption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a Federal agency decides to step into a field, its regulations will be exclusive. Such a rule, of course, would be inconsistent with the Federal-State balance embodied in our Supremacy Clause jurisprudence [citation omitted].
>
> Moreover, because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements, and responses to comment we can expect that they will make their intentions clear if they intend for their regulations to be exclusive. Thus, if an agency does not speak to the question of preemption, we will pause before saying that the mere

volume and complexity of its regulations indicates that the agency did in fact intend to preempt.

Hillsborough County v. Automated Medical Laboratories, 471 US 707; 105 SCt 2371; 85 LEd 2d 714, 724 (1985); California Coastal Commission v. Granite Rock Co., 480 US 572; 107 SCt 1419; 94 LEd 2d 577, 593 (1987).

The silence of the Federal statute and regulations with respect to E. Coli "takes on added significance in light of Congress' failure to provide any Federal remedy for persons injured by" E. Coli. Silkwood, supra, 464 US, at p.251. Now that the Federal agency considers E. Coli-contaminated meat to be "adulterated," it would appear that Plaintiffs have a claim under Michigan common law which is not preempted. After all, This Honorable Court just held recently that claims are not preempted if they are based on allegations that the Defendant negligently failed to comply with duties which are equal to or substantially identical to, requirements imposed by Federal law or regulation. Medtronic, Inc. v. Lohr, 135 LEd 2d 700, 721-723 (1996).

But Plaintiffs need not rely on the consistency of their claims with federal law. This Honorable Court has also held, in multiple decisions, that where there is no Federal regulation on point, there is no preemption. As the Court noted in Freightliner Corp. v. Myrick, 514 US 280; 115 SCt 1483; 131 LEd 2d 385, 393-94 (1995).

This Honorable Court reached the same conclusion in Medtronic v. Lohr, with respect to some of the Plaintiffs' claims. In Medtronic, the agency had simply allowed certain devices which were substantially equivalent to ones which existed before 1976 to be marketed without running the gauntlet of regulatory approval. 135 LEd 2d 700, 720-21. Thus, as to certain devices, there was no effective or real regulation whatsoever. In the absence of a specific regulation or specific requirement applicable to a particular device, there was no preemption. 135 LEd 2d at 723-24.

The same situation exists in this case. We invite the Court to consider the language of the preemption sections of the several statutes at issue here, and in Medtronic and Freightliner, supra. In Medtronic, the statute provided that the states could not, "with respect to a device intended for human use any requirement...which is different from, or in addition to, any requirement applicable under this Chapter," or which "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Chapter." The "Safety Act" at issue in Freightliner v. Myrick, supra provided, in its express preemption clause, that the states could not establish or continue "any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard." In this case,

the Federal Meat Inspection Act provides, at 21 USC Sec. 678, that the states may not create marking, labeling, packaging or ingredient requirements in addition to, or different than, those made under the Federal meat inspection law.

There was nothing "made" as to E. Coli in 1993; there is no preemption. That the Federal government subsequently acted to consider E. Coli-infected meat "adulterated", thus rendering Plaintiffs' claims consistent with Federal law (and not preempted in that event; Medtronic v. Lohr, supra), can hardly mean that there is preemption as to claims arising at a time when there was no Federal regulation at all![3] See also, Jacobs v. E.I. DuPont & Co., 67 F3d 1219, 1234-35 (CA6, 1995) (where the Food and Drug Administration never issued regulations specific to a particular medical device, the preemptive force of the medical device amendments never applied to the Plaintiffs' claims).

Indeed, it was not impossible to comply with MCLA 289.586, as well as Federal law, because Federal law did not preclude the

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[3] Note that Justice Breyer joined in enough of the lead opinion in Medtronic v. Lohr for each of the principles for which it is cited above to constitute the opinion of the Court. See, 135 LEd 2d at p.730 (Breyer, J., concurring opinion). At any rate, the Michigan Supreme Court has since embraced all of the pertinent aspects of the Medtronic v. Lohr analysis. Walker v. Johnson & Johnson, 217

states from regulating E. Coli-infected beef as being "adulterated." There was no Federal regulation specifically providing that E. Coli-infected beef is "not adulterated," as there was in the instance of trichinosis. Kircos, supra. Although, prior to 1994, the Federal government permitted the sale of E. Coli-infected beef, it did not approve of same, unlike the situation in Kircos, supra. There was no change in the statute in 1994; but rather, merely a bureaucratic realization that, as it had been forever, E. Coli-infected beef is "adulterated" for purposes of Federal law. It was not deemed unadulterated prior to that time, by any official agency action; there was simply raw inaction on the federal government's part.

The Circuit Court's refusal to see the distinctions between this case and Kircos, supra, and on reconsideration, the Circuit Judge's failure to see the significance of the Medtronic v. Lohr, preemption analysis (Opinions and Orders rendered: 6/25/96 and 8/12/96) constitute legal error. Although it is obviously true that Medtronic v. Lohr did not involve meat, but medical devices, it is equally true that the Medtronic preemption analysis, and that rendered by This Honorable Court in other preemption decisions, controls the proper resolution of this issue.

Mich App 705, 710-721 (1996).

Plaintiffs' claims are consistent with the public health purpose of the Federal Meat Inspection Act. Congress further expressed this intent at 21 USC Sec. 661(a):

> It is the policy of the Congress to protect the consuming public from meat and meat food products that are adulterated or misbranded and to assist in efforts by state and other government agencies to accomplish this objective (emphasis added).

The Circuit Court's decision, if it represents the law of the land, would bar all relief for persons injured by E. Coli-infected beef, if the wrong occurred prior to the federal realization that such meat is adulterated, in 1994. Defendants' argument, and the Circuit Court's decision, are not only unpersuasive, but also "implausible," for this very reason. Medtronic v. Lohr, 135 LEd 2d 700, 716. They would "have the perverse effect of granting complete immunity from...liability to an entire industry that," it was shortly thereafter determined, needed "more stringent regulation" in order to provide for the health of beef consumers. Id, 716-17.

III. THE COURT OF APPEALS MISCONSTRUED RYAN V BRUNSWICK CORPORATION, AND RYAN IS DISTINGUISHABLE FROM THE INSTANT CASE.

The instant Court of Appeals decision failed to even discuss Kircos v Holiday Foods; the case the trial court found controlling. This is a tacit admission that the trial court's reliance upon the authority of Kircos was as the Plaintiff argued, clearly erroneous.

The Appellate Court instead relied solely upon Ryan v Brunswick, 454 Mich 20, 557 NW2d 541 (1997).

There is an important factual distinction between Ryan, supra and the instant case. Ryan addressed a product liability suit involving adding propeller guards to recreational boats. The instant case is a question of whether Michigan has a right to protect its citizens from impure or poisoned food or water. Contaminated food and water was the genesis of product liability law. Traditionally, selling contaminated food or water is strict liability in tort. While the people of Michigan can do without a jet ski, they cannot live with contaminated food. Few things can cause as much public fear and harm as an outbreak caused by contaminated food. Our food supply must be protected by product liability suits.

The Court of Appeals has misconstrued this Honorable Court's ruling and reasoning in Ryan. The appeals court stated:

> "In Ryan supra p. 35, the Supreme Court made it clear that when a federal agency has 'deliberately concluded that regulation is not appropriate in a given area, federal inaction will preempt state law not identical to it.' That principle applies here. As previously noted, until 1994, the USDA did not consider E. Coli to be an "adulterant". Therefore, the Department did not consider it necessary to inspect for E. Coli and allowed the distribution of E. Coli contaminated meat.".
>
> (Opinion page 2, emphasis added).

Plaintiffs have underlined the word "therefore" to emphasis that the Court of Appeals inferred that the FDA had "deliberately concluded" not to declare expressly that E. Coli 0157:H7 was an adulterant. This is a false, material fact. There was no factual evidence before the Court that the FDA conducted such a hearing or developed such a policy.

The Michigan Appellate Court misconstrued Texas Food Industry Association et al. v Espy, 870 F.Supp 143 (1994). In Texas Food the meat industry was suing to prevent the FDA from implementing microbial batch testing for E. Coli 0157:H7 contamination on the production line. The food industry did not dispute that E. Coli 0157:H7 was an adulterant and a deadly pathogen but merely wanted to buy more time before the industry would have to test for its presence. The industry complained that the FDA did not jump through the necessary administrative procedures of having a notice and comment period before implementing the new testing regulations. While the meat industry was cynically arguing about how many angels can dance on the head of a pin, people were dying and profits were being made.

The district court in Texas Food Industry v Espy concluded that the FDA did not promulgate a "new" regulation but rather the decision to implement microbial testing an "interpretive" decision

and notice and hearing was not required in order for the regulation to be valid. Interpret means E. Coli was an "adulterant" at all times but now the political body could not ignore the deaths anymore.

In contradistinction, in the Michigan Supreme Court's opinion in Ryan the Court painstakingly researched the congressional intent in regard to the decision not to require guards on boat propellers. The Michigan Supreme Court noted that the United States Coast Guard had been delegated congressional authority to research and decide the issue of whether or not guards on boat propellers would enhance public safety.

The Coast Guard in conjunction with the National Boating Safety Advisory Council made an actual finding that propeller guards might actually lead to more casualties. Thus, the issue of whether safety guards should be added to propellers was not simply ignored but rather was intentionally rejected.

The Michigan Supreme Court went on to state:

> "A decision not to regulate does not automatically invoke preemption, but may carry the force of a positive enactment. Nevertheless, when a federal agency has actively analyzed the proposed area of regulation and has deliberately concluded that regulation is not appropriate in a given area, federal inaction will preempt state law not identical to it. This is not to say that inaction indicated preemption, but rather that " '[w]here a comprehensive federal *36 scheme intentionally leaves a portion of the regulated field without controls, then preemptive inference can be drawn—not from federal inaction alone, but from inaction joined with action.' " Ryan, supra at pp. 15, 16 (citations omitted)

Here E. Coli 0157:H7 was always an adulterant and the substantive change in 1994 after thousands of deaths, was the decision to add microbial batch testing on production runs and also to aggressively declare E. Coli's adulterant status. Unlike propeller guards in the Ryan case there was no intentional inaction combined with action as this Honorable Court requires to find preemption where an area of congressional authority is left unregulated.

IV. IT IS THE OFFICIAL OPINION OF THE UNITED STATES GOVERNMENT THAT MICHIGAN WRONGLY FOUND IMPLIED PREEMPTION IN RYAN V BRUNSWICK.

The Court of Appeals believed it was compelled by the Michigan Supreme Court's holding in Ryan v Brunswick, 454 Mich 20, 557 NW2d 541 (1997) to find that federal inaction implies preemption and immunity from state tort claims. (See Court of Appeals Opinion, last paragraph, page 3)

This Honorable Court granted certiorari in case number 97-288 of the 11 Circuit Court decision in Lewis v Brunswick Corporation, 107 F3d 1494 (1997) (A copy of which is attached as Appendix C) The case of Lewis v Brunswick Corporation is identical to Michigan's Ryan v Brunswick Corporation supra.

On July 30, 1998 This Honorable Court dismissed its writ of certiorari pursuant to Rule 46.1 (See Westlaw Bulletin attached as Appendix D) Plaintiff's counsel spoke with plaintiff's attorney in Lewis v Brunswick. The plaintiff and defendant in the Lewis v Brunswick Corporation came to a financial settlement the day before This Honorable Court was scheduled to release its opinion. This Plaintiff-Appellant/Appellant has a strong reason to believe that This Honorable Court was going to overrule Lewis v Brunswick Corporation and find that there was no preemption of state law negligence in product liability claims against an outboard engine manufacturer premised on the failure to provide a propeller guard where the coastguard had intentionally omitted a requirement for a propeller guard. That is, whether torts of omission are impliedly preempted under the acts while torts of commission are simultaneously expressly safe from preemption.

The Solicitor General of the United States filed an amicus curie brief supporting the petitioners in Lewis v Brunswick Corporation on behalf of the United States Government. The brief of the Solicitor General is attached as Appendix E. Michigan's Ryan v Brunswick Corporation is discussed in the brief.

The Solicitor General's brief needs no elaboration by this writer. It is clear that where the federal government itself does not

claim that state torts claims are barred in cases like the instant Boulahanis and Sowerby claims any state decision barring such a claim is erroneous.

REQUESTED RELIEF

Plaintiffs-Appellants/Appellants request this Honorable Court peremptorily reverse the Judgments of the Court of Appeal and the trial court and remand to the trial court for further proceedings on the Plaintiffs' product liability claims.

In the alternative, please accept this Appeal for consideration by this Honorable Court.

Respectfully submitted,

CHRISTOPHER E. PENCAK, P.C.

By: Christopher Pencak

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Dated: 6/23/99

APPENDIX A

COURT OF APPEALS ORDER

STATE OF MICHIGAN

COURT OF APPEALS

KAREN BOULAHANIS, GEORGE BOULAHANIS, BRIDGIT BOULAHANIS, KARA BOULAHANIS, and BRIAN BOULAHANIS,

Plaintiffs-Appellants,

FOR PUBLICATION
June 2, 1998
9:00 a.m.

v

PREVO'S FAMILY MARKET, INC., IBP, INC., and SPARTAN STORES, INC.,

Defendants-Appellees.

No. 197343
Mason Circuit Court
LC No. 94-10-358 NP

JANIS SOWERBY, Personal representative of the Estate of SCOTT MICHAEL HINKLEY,

Plaintiff-Appellant,

V

PREVO'S FAMILY MARKET, INC., IBP, INC., and SPARTAN STORES, INC.,

Defendants-Appellees.

No. 197344
Mason Circuit Court
LC No. 94-10-343 NP

Before: MacKenzie, P.J., and Holbrook, Jr. and Saad, JJ.

Nature of the Case and Background

These consolidated cases involve breach of implied warranty and negligence claims that plaintiffs brought after consuming ground beef contaminated with Escherichia CoR 0157:H7 (E. Coli), a pathogen found in the fecal matter of cattle that can be spread when it is intermixed with ground meat products. The contaminated meat was produced by defendant 113P, Inc., distributed by defendant Spartan Stores, and sold by defendant Prevo's Family Market in mid-July 1993. After consuming the meat, plaintiffs Kara and Brian Boulahanis, who are minor children o plaintiffs Karen and George Boulahanis, became seriously ill with hemolytic uremic syndrome (HUS) caused by E. Coli bacteria. Plaintiffs Bridgit and Karen Boulahanis became less seriously ill. Three-year-old Scott Michael Hinkley, the son of plaintiff Janice Sowerby, died from E. Coli associated HUS. Plaintiffs appeal as of right from an order granting summary disposition to defendants on the basis that plaintiffs' claims are preempted by the Federal Meat Inspection Act, as amended by the Wholesome Meat Act, 21 USC 601 *el seq.* (MA), and its regulations. We affirm.

Analysis

A. The Federal Meat Inspection Act

The purpose of the FMIA is to assure that meat distributed to consumers is wholesome, not adulterated, and properly marked, labeled, and packaged. 21 USC § 602. Generally, the act sets standards for acceptable meat and meat products, provides for inspections by the United States Department of Agriculture, and requires that meat "found to be not adulterated shall be marked, stamped, tagged, or labeled as 'Inspected and passed.'" 21 USC § 604. The term "adulterated" is defined at 21 USC § 601(m). 21 USC § 601(m)(1) provides:

> (m) The term "adulterated" shall apply to any ... meat. . ,

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health.

Prior to 1994, which is prior to the date that plaintiffs' actions arose, the USDA did not consider meat and poultry bearing pathogen such as E. Coli or salmonella to be **"adulterated" and did not require meat** producers to test for the presence of these bacteria. *Texas Food Industry Assn v Espy,* 870 F Supp 143, 145 (AD Tex, 1994). Nor did the FMIA require inspection or investigation to detect the presence of the pathogens.

On October 17, 1994 the USDA announced its decision to treat E. Coh as an adulterant and gave notice of a new E. Coli sampling program. Texas *Food Industry, supra,* p 145. In 1996, 9 CFR § 25 was promulgated. That regulation recognizes E. Coli and salmonella as adulterants, requires sampling of livestock carcasses for E. Coh testing, and sets criteria for evaluation of test results.

B. Federal Preemption

Federal preemption is either express or implied. *Ryan v Brunswick Corp,* 454 Mich 20, ~8; 557 NW2d 541 (1997). If express, the intent of Congress to preempt state law must be clearly stated in the statute's language or impliedly contained in the statute's structure and purpose. Id In the absence of express preemption, implied preemption may exist in the form of field or conflict preemption. Id. Field preemption may be found where the state law at issue regulates conduct in a field that Congress intended the federal government to occupy exclusively, See *Martinez v Ford Motor Co,* 224 Mich App 247, 252; 568 NW2d 396 (1997). Conflict preemption exists when it is impossible to comply with both state and federal law, or where the state law stands as an obstacle to the accomplishment of Congress' objectives. *Kircos v Holiday Food*

Center, Inc, 191 Mich App 82, 86; 477 NW2d 130 (1991); *Martinez, supra.* Conflict preemption is compelled not only when a state law is in conflict with a federal statute, but also when it conflicts with a valid federal regulation. Kircos, *supra, p 86.* Conflict preemption is also compelled when a state law is in conflict with a federal regulatory agency's intentional decision *not* to regulate. *Ryan, supra, pp* 35-36. Furthermore, the state "law" in conflict with a federal statute or regulation need not be a state statute; state common law causes of action may constitute state regulation subject to preemption if the cause of action would impose, through an award of damages, a requirement not found in federal law. Id., p 34.

The FN41A includes an express federal preemption provision. 21 USC § 678 reads in

> Requirements within the scope of this chapter with respect to . . . any establishment at which inspection is provided ... which are in addition to, or different than those made under this chapter may not be imposed by any State.... Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State ... but any State . . . may, consistent with the requirements under this chapter, exercise concurrent jurisdiction with the Secretary [of Agriculture] over articles required to be inspected . . . for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment.

Based on this language, it is clear that Congress has expressly preempted states from expressly preempted states from placing any additional or different requirement, on meat producers other than those of the federal government. See, e.g., *Annour & Co v Ball,* 468 F2d 76 (1972). Under *Ryan* and *Martinez, supra,* any state tort action based on a theory that adulterated meat was distributed must therefore be based on standards that are identical to federal standards.

Plaintiffs contend that their tort claims are not preempted by federal law because neither Congress nor the USDA adopted regulations concerning the presence of E. Coli bacteria in meat products until 1994, the year after plaintiffs purchased the tainted meat in this case. They reason that because there were no regulations explicitly allowing the sale of meat contaminated with pathogens such as E. Coli or salmonella at the time of their injuries, state law claims based on the sale of E. Coh-contaminated meat do not conflict with then-existing federal law and should be allowed. We disagree.

In Ryan, supra, p 35, the Supreme Court made it clear that when a federal agency "has deliberately concluded that regulation is not appropriate in a given area, federal inaction will preempt state law not identical to it." That principle applies here. As previously noted, until 1994, the USDA did not consider E. Coli to be an "adulterant." Therefore, the Department did not consider it necessary to inspect for E. Coli and allowed the distribution of E. Colicontaminated meat. The justification was that the painstaking microscopic inspection of meat for pathogens such as E. Coli and salmonella was not feasible and not warranted when any bacteria would eventually be destroyed by the consumer upon **proper preparation and cooking of the meat.** See *American Public Health Assn v Butz,* 167 US App DC 93; 511 F2d 331, 332, 334 (1974). This intentional decision, not to regulate the presence of E. Coh because it was not considered an adulterant, carries the force of a positive enactment. *Ryan, supra.* Holding defendants liable for failing to detect the presence of E. Coh bacteria in the meat purchased by plaintiffs in 1993 would run contrary to the USDA's then-existing determination thaf inspection for E. Coli bacteria was not required. The trial court therefore properly concluded that plaintiffs' claims were preempted by federal law.

Affirmed.
/s/ Barbara B. MacKenzie
/s/ Donald E. Holbrook, Jr.
/s/ Henry William Saad

APPENDIX B

CIRCUIT COURT OPINION AND ORDER

STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF MASON

KAREN BOULAHANIS, GEORGE BOULAHANIS, Individually and as Next Friend of BRIDGIT BOULAHANIS, KARA BOULAHANIS, and BRIAN BOULAHANIS, Minors,

Plaintiffs, File No. 94-10-358-NP

-vs

PREVO'S FAMILY MARKET, INC., I.B.P., INC., and SPARTAN STORES,

Defendants.

and

JANIS SOWERBY, as Personal Representative of the Estate of Scott Michael Hinkley, deceased,

Plaintiff,

-vs

File No. 94-10-343-NP

PREVO'S FAMILY MARKET, INC., I.B.P., INC., and SPARTAN STORES, INC.,

Defendants.

_____/

OPINION AND ORDER REGARDING DEFENDANTS' MOTION FOR SUMMARY DISPOSITION

Oral arguments were heard on Defendants' Motions for Summary Disposition on April 22, 1996. Plaintiffs were represented by Attorney Christopher Pencak and Defendants were represented by Attorneys William Mills, Thomas Wurst, and Chuck Worsfold. The Court has had the benefit of hearing briefs as well as post hearing briefs dated May 7, 1996 and May 10, 1996 by Defendant Prevo's and Plaintiff Pencak respectively.

Plaintiffs had purchased and consumed ground beef which had been purchased from Defendant Prevo's during July, 19903. Piaintiffs contend that the ground beef was contaminated with Escherichia Coli 0157:H7 which, after consumption, caused serious injury to all Plaintiffs and which caused the death of Scott Michael Hinkley on July 30, 1993 due to Hemolytic Uremic Syndrome (HUS).

Defendants contend that at the time the ground beef was furnished and consumed, that the Federal Meat Inspection Act had not yet declared Escherichia Coli 0157:H7 bacteria to be an "adulterant" and that all meat sold had passed inspection by federal inspectors at the slaughter house. By passing inspection, **the meat was** deemed fit for shipping and distribution. Further, Defendants contend that the Federal Meat Inspection Act specifically prohibits States from mandating warning labels other than that utilized by the Federal Meat Inspection Act and Wholesome Meat Act. The pertinent part of the Act reads as follows:

> "Requirements within the scope of this chapter with respect to . . . any establishment at which inspection is provided ... which are in addition to, or different than those made under this chapter may not be impos~d by any State ... Marking, labeling, packaging, or ingredient

requirements in addition to, or different than, thoV made under this chapter may not be imposed by any State . . -but any State . . . may, consistent with the requirements under this chapter, exercise concurrent jurisdiction . . . for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated . . . and are outside of such an establishment." The Federal Meat Inspection Act (21 USC601, et seq, as amended by the Wholesale Meat Act, 21 USC sec 601-95).

Finally, Defendants rely upon the Michigan case Kircos v Holiday Food Center, 191 Mich App 82 (1991), for the principal that federal meat inspection laws and regulations preempt state law and that said case specifically disallows any state tort claim of negligence and or breach of warranty.

Clearly the Federal Meat Inspection Act as denoted above preempts any requirement that Defendants had a responsibility to provide warning labels on the ground beef different or in addition to that required by the Wholesome Meat Act. The Act also clearly says States cannot impose additional or different inspection requirements. Despite the meritorious argument that Escherichia Coli contamination was known by the meat industry to be an adulteration in 1993, the federal regulations and/or statutes had not yet reached that determination in July of 1993 when the present cause of action arose. The Mason County Trial Court is bound by the Court of Appeals determination in Kircos which parallels present Defendants' preemptive argument that. where no warning labels were required by the Federal Meat Inspection Act nor the Wholesome Meat Act, then no warning labels would be required in Michigan. The same conclusion applies to inspection/testing requirements. In Kircos the Defendants were a retail food store and a meat packer which engaged in Interstate Commerce as is true in our present case.

Further, this Court is bound by the Kircos ruling that there can be no recovery under state tort law. Because federal law and regulation had not in 1993 determined Escherichia Coli to be an adulterant, food retailers and meat packers were not required to test for or treat meat in 1993 for Escherichia Coli contamination. Plaintiffs make a well reasoned argument that Defendants should have known better and/or tested on their own because the industry knew of such dangers whereas the general public did not. However as observed above, the Kircos case specifically states that this subject area is preempted by federal law and regulation and that a tort claim cannot be utilized. to seek recovery. Plaintiffs' present claims rest in negligence and implied warranty which are both tort actions.

This Court had expressed an interest in the Jack-in-the-Box cases. Plaintiffs have provided several attorney affidavits whereby the Court's question is answered that preemption was not utilized as a defense in virtually all of those cases. However Defendants are correct when they observe that the liability in the Jack-in-theBox cases had to do with improper cooking; i.e., the various restaurants had not cooked the "hamburgers" sufficiently long and/or at a high enough temperature so that the Escherichia Coli would be destroyed in the cooking process. Under state health department regulations and or general sanitation food practices the restaurants failed to serve safe food. That failure is distinct from federal laws and regulations regarding the labeling, inspection/testing, and distribution of raw meat. The failure to cook properly made the restaurants liable for negligence in the Jack-in-the-Box cases. Since 1993, federal regulations have denoted that Escherichia Coli is an adulterant, thus under current federal law the ground beef purchased by Plaintiffs would have received some testing requirement protection which did not exist in July 1993.

Defendants' Motions for Summary Disposition **are GRANTED.**

Date: June 25, 1996

_____

/S Richard I. Cooper, Circuit Judge

APPENDIX C

US SUPREME COURT GRANTING CERTIORARI OF THE CIRCUIT COURT DECISION IN LEWIS V. BRUNSWICK

107 F.3d 1494
65 USLW 2642, 1997 A.M.C. 1921, Prod.Liab.Rep.
(CCH) P 14,903,
97 FCDR 1601,
10 Fla. L. Weekly Fed. C 767
(Cite as: **107 F.3d 1494**)

Vicky LEWIS, individually as parent, as next friend and as administrator of the estate of Kathryn C. Lewis, Gary Lewis, individually as parent, as next friend and as administrator of the estate of Kathryn C. Lewis, Plaintiffs-Appellants,

V.

BRUNSWICK CORPORATION, Defendant Appellee.

No. 96-8130.

United States Court of Appeals,
Eleventh Circuit.

March 21, 1997.

Parents of recreational boat passenger who died after she fell or was thrown from boat and was struck by the boat's propeller brought suit in state court against manufacturer of boat's outboard engine, asserting negligence and strict liability claims based on absence of propeller guard. Parents also asserted fraudulent misrepresentation claims, based on contention that manufacturer misrepresented performance differences between guarded engines and unguarded engines to discourage government agencies from adopting safety standard requiring propeller guards. After removal, the United States District Court for the Southern District of Georgia, No. CV 195-096, Dudley H. Bowen, Jr., J., 922 F.Supp. 613, granted summary

judgment in favor of manufacturer on ground that claims were preempted by the Federal Boat Safety Act (FBSA), and plaintiffs appealed. The Court of Appeals, Carnes, Circuit Judge, held that: (1) text of the FBSA does not provide clear manifestation of intent to preempt claims, and thus they were not expressly preempted; (2) position of Coast Guard rejecting propeller guard requirement is tantamount to a ruling that no such requirement may be imposed, and that position impliedly preempts state law requirements of propeller guards, even in the form of common-law state tort claims; and (3) Coast Guard position on propeller guards also preempted fraudulent misrepresentation claim.

Affirmed.

[11 FEDERAL COURTS c&;-776

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Decision of district court granting summary judgment on ground of preemption was subject to de novo review.

[21 STATES (&=18.5 36Okl8.5

Any state law that conflicts with federal law is preempted by the federal law and is without effect under the supremacy clause of the Constitution. U.S.C.A. Const. Art. 6, cl. 2.

[31 STATES (Z~=18.11

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State regulation established under historic police powers of the states is not superseded by federal law unless preemption is the clear and

manifest purpose of Congress; thus, intent of Congress is the touchstone of preemption analysis.

[31 STATES (Z~:-18.13

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State regulation established under historic police powers of the states is not superseded by federal law unless preemption is the clear and manifest purpose of Congress; thus, intent of Congress is the touchstone of preemption analysis.

[41 STATES (2=18.3

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Congressional intent to preempt state law may be revealed in several ways: "express preemption," in which Congress defines explicitly extent to which its enactments preempt state law; "field preemption," in which state law is preempted because Congress has regulated a field so pervasively, or federal law touches on a field implicating such dominant federal interest, that an intent for federal law to occupy the field exclusively may be inferred; and "conflict preemption," in which state law is preempted by implication because state and federal law actually conflict, so that it is impossible to comply with both, or state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

See publication Words and Phrases for other judicial constructions and definitions.

[51 STATES **(S:-18.13**
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107 F.3d 1494

state law requirements of propeller guards, even in form of common-law tort claims. 46 U.S.C.A. § 4301 et seq.

Page 4

[111 STATES (~~;-18.65

360kl8.65

State common-law negligence and product liability claims against manufacturer of boat engine, based on theory that engine was defective because it lacked a propeller guard, were impliedly preempted by the Federal Boat Safety Act; because Congress has made the Coast Guard the exclusive authority in the area of boat and equipment safety standards, its position rejecting propeller guard requirement is tantamount to ruling that no such requirement may be imposed, and that position impliedly preempts state law requirements of propeller guards, even in form of common-law tort claims. 46 U.S.C.A. § 4301 et seq.

[121 PRODUCTS LIABILITY c~z-62

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Product liability claims based on defective design or installation of products that are already installed, as opposed to claims based on failure to install a certain device, are not impliedly preempted under the Federal Boat Safety Act (FBSA); permitting such claims against manufacturers for negligent or defective design of products required by the Coast Guard, or product provided voluntarily by manufacturers, simply requires manufacturers to comply with FBSA regulations, and is consistent with the FBSA scheme; however, claims based on failure to install product that Coast Guard has decided should not be required would conflict with purpose of the FBSA to insure regulatory uniformity. 46 U.S.C.A. § 4301 et seq.

[12] STATES (:9:;-18.65

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Product liability claims based on defective design or installation of products that are already installed, as opposed to claims based on failure to install a certain device, are not impliedly preempted under the Federal Boat Safety Act (FBSA); permitting such claims against manufacturers for negligent or defective design of products required by the Coast Guard, or product provided voluntarily by manufaqturers, simply requires manufacturers to comply with FBSA regulations, and is consistent with the FBSA scheme; however, claims based on failure to install product that Coast Guard has

decided should not be required would conflict with purpose of the FBSA to insure regulatory uniformity. 46 U.S.C.A. § 4301 et seq,

[131 PRODUCTS LIABILITY -62

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State law fraudulent misrepresentation claim against manufacturer of boat engine, seeking to impose liability upon manufacturer for attempting to persuade the Coast Guard and others that propeller guards are unsafe, was impliedly preempted by Coast Guard's position that propeller guards should not be required under the Federal Boat Safety Act; necessary element of causation in claim was that but for wrongful conduct of manufacturer, propeller guards would have been required by Coast Guard; however, such judgment conflicted with Coast Guard's position that propeller guards should not be required. 46 U.S.C.A. § 4301 et seq.

[131 STATES (9~=18.65

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State law fraudulent misrepresentation claim against manufacturer of boat engine, seeking to impose liability upon manufacturer for

attempting to persuade the Coast Guard and others that propeller guards are unsafe, was impliedly preempted by Coast Guard's position that propeller guards should not be required under the Federal Boat Safety Act; necessary element of causation in claim was that but for wrongful conduct of manufacturer, propeller guards would have been required by Coast Guard; however, such judgment conflicted with Coast Guard's position that propeller guards should not be 4required. 46 U.S.C.A. § 4301 et seq.

*1496 David E. Hudson, William James Keogh, 111, Hull, Towill, Norman & Barrett, Augusta, GA, for plaintiffs -appellants.

*1497 Ronald L. Reid, James W. Hagan, Alston & Bird, Atlanta, GA, Daniel J. Connolly, Faegre & Benson, Minneapolis, MN, for defendant-appellee.

Appeal from the United States District Court for the Southern District of Georgia.

Before BIRCH, BLACK and CARNES, Circuit Judges.

CARNES, Circuit Judge:

Gary and Vicky Lewis appeal the district court's

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in areas traditionally regulated, by the states through their police powers, Court of Appeals applies presumption in favor of narrow interpretation of an express preemption clause.

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.Because the Federal Boat Safety Act preempts area of safety that historically has been regulated by the states through their police powers, Court of Appeals must construe the Act's preemption clause narrowly. 46 U.S.C.A. § 4306.

[61 STATES <E~=18.65 360k18.65

Because the Federal Boat Safety Act preempts area of safety that historically has been regulated by the states through their police powers, Court of Appeals must construe the Act's preemption clause narrowly. 46 U.S.C.A. § 4306.

[71 PRODUCTS LIABILITY (2Z-62

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Express preemption clause of the Federal Boat Safety Act does not cover common- law state tort claims; although preemption clause could be read to cover such claims, savings clause indicates that at least some common-law claims survive express preemption, and resulting doubt must be resolved in favor of narrower interpretation; however, conflict between express preemption clause and savings clause precludes any conclusion that such claims are expressly saved. 46 U.S.C.A. § 4306.

[71 STATES 1:~:=18.65

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Express preemption clause of the Federal Boat Safety Act does not cover common- law state tort claims; although preemption clause could be read to cover such claims, savings clause indicates that at least some common-law claims survive express preemption, and resulting doubt must be resolved in favor of narrower interpretation; however, conflict between express preemption clause and savings

clause precludes any conclusion that such claims are expressly saved. 46 U.S.C.A. § 4306.

[81 PRODUCTS LIABILITY 1!2~;-62

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St~te tort claims are impliedly preempted under the Federal Boat Safety Act (FBSA) if they prevent or hinder the FBSA from operating the way Congress

intended it to operate; in deciding whether claims conflict with purposes of the FBSA, Court of Appeals does not apply presumption against preemption, even though common-law tort claims are mechanism of police powers of the state, as relative importance to the state of its own law is not material when there is a conflict with a valid federal law. 46 U.S.C.A. § 4301 et seq.

[81 STATES (&:-18.65

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State tort claims are inipliedly preempted under the Federal Boat Safety Act (FBSA) if they prevent or hinder the FBSA from operating the way Congress intended it to operate; in deciding whether claims conflict with purposes of the FBSA, Court of Appeals does not apply presumption against preemption, even though common-law tort claims are mechanism of police powers of the state, as relative importance to the state of its own law is not material when there is a conflict with a valid federal law. 46 U.S.C.A. § 4301 et seq.

[91 STATES c&:-18.3 36Okl8.3

Federal decision to forego regulation in given area may imply an authoritative federal determination that area is best left unregulated,

and in that event would have as much preemptive force as a decision to regulate.

[10] STATES (9=18.3

360kl8.3

Although federal decision not to regulate does not always have preemptive effect, it does have such where failure of federal officials affirmatively to exercise their full authority takes on character of a ruling that no such regulation is appropriate or approved pursuant to policy of statute.

[111 PRODUCTS LIABILITY (&=62

313Ak62

State common-law negligence and product liability claims against manufacturer of boat engine, based on theory that engine was defective because it lacked a propeller guard, were impliedly preempted by the Federal Boat Safety Act; because Congress has made the Coast Guard the exclusive authority in the area of boat and equipment safety standards, its position rejecting propeller guard requirement is tantamount to ruling that no such requirement may be imposed, and that position impliedly preempts

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107 F.3d 1494

(Cite as: 107 F.3d 1494, *1497)

grant of summary judgment in favor of Brunswick corporation ("Brunswick") on the Lewises' state common law negligence, product liability, and fraudulent misrepresentation claims. The Lewises sued Brunswick to recover damages for the death of their daughter, who died after she fell or was thrown from a boat and then struck by a Brunswick engine ,propeller. According to the Lewises,

the Brunswick engine involved in their daughter's death was defective because it lacked a propeller guard. Upon Brunswick's motion for summary judgment, the district court held that the Lewises' claims were preempted by the Federal Boat Safety Act, 46 U.S.C. §§ 4301-4311 ("the FBSA" or "the Act"). We affirm.

In Part I of this opinion, we describe the facts and the procedural history of this case. We describe the standard of review in Part 11, and we outline the Act and its regulatory scheme in Part 111. In Part IV, we recount the actions taken by the Coast Guard regarding propeller guards. We then summarize the positions of the parties in Part V of the opinion. In Part VI, we describe in general terms how state law may be preempted. We then proceed to consider, in Parts VII and VIII of the opinion, whether the Lewises' claims are preempted by the Act.

As we will explain in Part VII, the preemption clause and the savings clause in the Act provide contradictory indications of congressional intent relating to whether the Lewises' claims are expressly preempted. Because the text of the FBSA does not provide a clear manifestation of intent to preempt the claims, we cannot hold that they are expressly preempted. On the other hand, due to the conflict between the preemption clause and the savings clause, we cannot hold that those claims are expressly saved from preemption either. Consequently, our resolution of the question of preemption in this case turns on whether the Lewises' claims are impliedly preempted by the Act. We hold that they are, because those claims conflict with the Coast Guard's position that propeller guards should not be required.

1. FACTS AND PROCEDURAL HISTORY

On June 6, 1993, Kathryn Lewis was spending the day with her boyfriend's family in a boat on Strom Thurmond Lake in Georgia. While the boat was pulling Kathryn's boyfriend on an inner tube, the

driver made a right-hand turn. Kathryn fell or was thrown from the left side of the boat. Once in the water, Kathryn was struck repeatedly in the head and body by the propeller of an engine designed and manufactured by Brunswick. The engine did not have a propeller guard. Kathryn died instantly.

The Lewises filed suit against Brunswick in Georgia state court, alleging that the lack of a propeller guard made the Brunswick engine a defective product. They also claim that Brunswick committed negligence by failing to install a propeller guard on the engine. The Lewises' third claim avers that Brunswick attempted to suppress the production of propeller guards by third persons and exaggerated the performance differences between guarded engines and unguarded engines to discourage government agencies from adopting a safety standard requiring propeller guards.

Brunswick removed this case to federal district court on diversity grounds and moved for summary judgment. In its summary judgment motion, Brunswick contended that all of the Lewises' claims were preempted by the FBSA. The district court agreed ***1498** and granted summary judgment in favor of Brunswick. The Lewises appeal.

11. STANDARD OF REVIEW

[1] We apply the same legal standards in our preemption analysis that the district court was required to apply in its order granting summary judgment; therefore, we review the district court's decision de novo. E.g., Southern Solvents, Inc. v. New Hampshire Ins. Co., 91 F.3d 102, 104 (Ilth Cir. 1996).

111. THE FEDERAL BOAT SAFETY ACT

The FBSA was enacted in 1971 in part "to improve boating safety by requiring manufacturers to provide safer boats and boating equipment to the public through compliance with safety standards to be promulgated by the Secretary of the Department in

which the Coast Guard is operating--presently the Secretary of Transportation." P.L. 92-75, Federal Boat Safety Act of 1971, S.Rep. No. 92-248, reprinted in 1971 U.S.C.C.A.N. 1333. To implement that goal, the Act grants authority to the Secretary of Transportation to prescribe regulations establishing minimum safety standards for

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recreational boats. See 46 U.S.C. § 4302 (West Supp.1995). The Secretary of Transportation has delegated rulemaking authority under the FBSA to the United States Coast Guard. See 49 C.F.R. § 1.46(n)(1) (1996).

The FBSA requires the Coast Guard to follow -certain guidelines and procedures when promulgating a regulation under 46 U.S.C. § 4302. For instance, the Coast Guard must consider certain available data and "the extent to which the regulations will contribute to recreational vessel safety. " 46 U.S.C.A. §§ 4302(c)(l)-(2) (West Supp.1995). The Coast Guard may not establish regulations compelling substantial alterations of existing boats and associated equipment unless compliance would "avoid a substantial risk of personal injury to the public." 46 U.S.C.A. § 4302(c)(3) (West Supp. 1995). Before promulgating a regulation, the Coast Guard is required to consult with the National Boating Safety Advisory Council ("the Advisory Council") on the need for regulation. 46 U.S.C. § 4302(c)(4).

IV. COAST GUARD CONSIDERATION OF A PROPELLER GUARD REGULATION

In 1988, the Coast Guard directed the Advisory Council to examine the feasibility and potential safety advantages and safety disadvantages of propeller guards. In response, the Advisory Council

appointed a Propeller Guard Subcommittee "to consider, review and assess available data concerning the nature and incidence of recreational boating accidents in which persons in the water are struck by propellers." National Boating Safety Advisory Council, Report of the Propeller Guard Subcommittee 1 (1989). The Advisory Council also asked the Subcommittee to consider whether "the Coast Guard [should] move towards a federal requirement for some form of propeller guard." Id. at Appendix A.

The Advisory Council Subcommittee held hearings on three occasions and received information from a variety of individuals and groups interested in the topic of propeller guards. See id. at 2-4. One of the matters on which the Subcommittee received information was propeller guard litigation, and the Subcommittee devoted a section of its report to the topic. Id. at 4. That section states that, at the time of the hearings, propeller guard advocates were

petitioning federal and state legislators to mandate propeller guards. According to the Subcommittee Report, a legislative or administrative mandate "would necessarily be predicated on the feasibility of guards and establish prima facie manufacturer liability in having failed to provide them"; therefore, feasibility was an important question before the Subcommittee. Id. at 5. The report also discusses the theories of liability that were being asserted by propeller guard victims and the defenses used by manufacturers. Id. at 4-5. **Immediately *1499** following that discussion, the report notes that "[mlanufacturers are opposed to mandatory propeller guards." Id. at 5.

The Subcommittee also considered the technical issues posed by propeller guards. After reviewing the available scientific data and testimony, the Subcommittee found that propeller guards affect boat operation adversely at speeds greater than 10 miles per hour. Id. at 2 1. Further, the Subcommittee found that propeller guards would not increase overall safety, because they increase the chances of contact

between a blunt object and a person in the water. Id. at 20-21. The Subcommittee Report states:

> Injuries/fatalities caused by underwater impacts result from a person coming into contact with the propeller or any part of the propulsion unit (i.e., lower unit, skeg, torpedo, anti-ventilation plate, etc.) and even the boat itself. Currently reported accidents make it obvious that all such components are involved in the total picture, **and that the** propeller itself is the sole factor in only a minority of impacts. The development and use of devices such as "propeller guards" can, therefore, be counter-productive and can create new hazards of equal or greater consequence.... Although the controversy which currently surrounds the issue of propeller guarding is, by its very nature, highly emotional and has attracted a great deal of publicity, there are no indications that.there is a generic or universal solution currently available or foreseeable in the future. The boating public must not be misled into thinking there is a "safe" device which would eliminate or significantly reduce such injuries or fatalities.

Id. at 23-24. The report also states that: boats and motors should be designed to incorporate technologically feasible safety features to avoid or minimize the consequences of inexperienced or negligent operation, without at the same time (a)

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creating some other hazard, (b) materially interfering with normal operations, or (c) being at economic costs disproportionate to the particular risk.

Proponents assert that propeller guard technology and/or availability meets the foregoing criteria and that guards should not be mandated. The Subcommittee does not agree....

Id. at 20. In its conclusion, the Advisory Council Subcommittee Report recommends that "[tjhe U.S. Coast Guard should take no regulatory action to require propeller guards." Id. at 24.

The Subcommittee presented its report to the entire Advisory Council, which accepted the report and adopted the recommendations of the Subcommittee. Minutes of ' the 44th Meeting of the National Boating Safety Advisory Council 19 (Nov. 6-7, 1989). The Advisory Council then forwarded the report and recommendations to the Coast Guard. The Coast Guard adopted each of the Advisory Council's recommendations, giving explanations of the Coast Guard's position on each matter. See Letter from Robert T. Nelson, Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation, Safety and Waterway Services to A. Newell Garden, Chairman, National Boating Safety Advisory Council (Feb. 1, 1990). The Coast Guard's position on propeller guards, which is set out in that letter, is as follows:

> The regulatory process is very structured and stringent propeller imposition
>
> regarding justification. Available guard accident data do not support of a regulation requiring propeller guards on motorboats. Regulatory action is also limited by the many questions about whether a universally acceptable propeller guard is available or technically feasible in all modes of boat operation. Additionally, the question of retrofitting millions of boats would certainly be a major economic consideration.
>
> The Coast Guard will continue to collect and analyze data for changes and trends; and will promote increased/improved accident reporting as addressed in recommendation 2. The Coast Guard will also review and retain any information made available regarding development and testing of new propeller guard devices or other information on the state of the art.

Id. at 1.

The Lewises contend that the FBSA does not expressly or impliedly preempt state law ***1500** tort claims based on the absence of a propeller guard on a boat engine. According to the Lewises, common law claims are expressly saved from preemption by the Act's savings clause. Furthermore, the Lewises argue, the Act does not preempt any state law, regulation, or claims until the Coast Guard issues a formal regulation on the matter. There being no regulation on propeller guards, the Lewises assert they may proceed with their case.

In response, Brunswick argues that the FBSA expressly preempts any state regulation, including regulation through common law claims, that conflicts with a Coast Guard regulation or regulatory position. Brunswick contends that the Coast Guard has made a regulatory decision that propeller guards cannot be required. For that reason, Brunswick says, the Lewises' claims are expressly preempted by the Act. Furthermore, even if the Lewises' claims are not expressly preempted, Brunswick argues that the claims conflict with the Coast Guard's position that propeller guards should not be required. For that reason, Brunswick contends, the claims are preempted by implication.

VI. AN OVERVIEW OF PREEMPTION DOCTRINE

[2][3] Any state law that conflicts with federal law is preempted by the federal law and is without effect under the Supremacy Clause of the Constitution. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407 (1992). State regulation established under the historic police powers of the states is not superseded by federal law unless preemption is the clear and

manifest purpose of Congress. Id. Accordingly, the intent of Congress is the touchstone of preemption analysis. See id.

[4] Congressional intent to preempt state law may be revealed in several ways: (1) "express preemption," in which Congress defines explicitly the extent to which its enactments preempt state law; (2) "field preemption," in which state law is preempted because Congress has regulated a field so pervasively, or federal law touches on a field implicating such a dominant federal interest, that an intent for federal law to occupy the field exclusively

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may be inferred; and (3) "conflict preemption," in which state law is preempted by implication because state and federal law actually conflict, so that it is impossible to comply with both, or state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Teper v. Miller, 82 F.3d 989, 993 (Ilth Cir.1996) ,(citations omitted).

[51 By including an express preemption clause in the FBSA, Congress has demonstrated its intent that the Act preempt at least some state law. See 46 U.S.C. § 4306. Therefore, the issue in this case is not whether Congress intended for the FBSA to have any preemptive effect, but the intended scope of preemption--the extent to which the FBSA preempts state law. See Medtronic, Inc. v. Lohr, --- U.S. ---
116 S.Ct. 2240, 2250, 135 L.Ed.2d 700
(1996). In areas traditionally regulated by the states through their police powers, we apply a presumption in favor of a narrow interpretation of an express preemption clause. Id. at 116 S.Ct. at 2250.

VII. EXPRESS PREEMPTION

Brunswick contends that the Lewises' claims fall within the scope of the FBSA's express preemption clause, which provides:

> Unless permitted by the Secretary under section 4305 of this title, a State or a political subdivision of a State may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment (except insofar as the State or political subdivision may, in the absence of the Secretary's disapproval, regulate the carrying or use of marine safety articles to meet uniquely hazardous conditions or ***1501** circumstances within the State) that is not identical to a regulation prescribed under section 4302 of this title.

46 U.S. C. A. § 4306 (West Supp. 1995). According to Brunswick, the Lewises' claims, if successful, would result in a regulation imposing a propeller guard requirement. That regulation would not be identical to--in fact, it would be in conflict with--the Coast Guard's position that propeller guards should not be required. In Brunswick's view, the Coast Guard's position is equivalent to a "regulation prescribed under section 4302," which preempts state law. Following this reasoning, Brunswick

argues that the Lewises' claims are preempted by the express terms of the FBSA preemption clause.

In response, the Lewises contend that the phrase "law or regulation" does not reach common law claims, because Congress did not mention "common law" specifically in the preemption clause. According to the Lewises, Congress' decision not to specify "common law" in the preemption clause demonstrates congressional intent to save common law claims. As Brunswick points out, however, the omission of the phrase "common law" in the preemption clause is not determinative, because "law" and "regulation" may be read to include state tort actions. See Cipollone,

505 U.S. at 520-30, 112 S.Ct. at 2619-25 (1992) (plurality opinion) (holding that the phrase "State law" in the Federal Cigarette Labeling and Advertising Act was intended to include common law claims); CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664, 113 S.Ct. 1732, 1737, 123 L.Ed.2d 387 (1993) (common law claims fall within the scope of the phrases "law, rule, regulation, order, or standard"). In fact, the overwhelming majority of courts have held that common law claims fall within the scope of "law[s]" and "regulation[s]" expressly preempted by the FBSA. See Moss v. Outboard Marine Corp., 915 F.Supp. 183, 186 (E.D.Cal.1996); Davis v. Brunswick Corp., 854 F.Supp. 1574, 1580 (N.D.Ga.1993); Shield v. Bayliner Marine Corp., 822 F.Supp. 81, 84 (D.Conn.1993); Shields v. Outboard Marine Corp., 776 F.Supp. 1579, 1581 (M.D.Ga.1991); Mowery v. Mercury Marine, 773 F.Supp. 1012, 1017 (N.D.Ohio 1991); Farrier v. Brunswick Corp., 239 Ill.App.3d 885, 180 Ill.Dec. 493, 497-98, 607 N.E.2d 562, 566-67 (1992); Ryan v. Brunswick Corp., 454 Mich. 20, 557 N.W.2d 541, 548-49 (1997). Contra Moore v. Brunswick Bowling & Billiards Corp., 889 S.W.2d 246, 250 (Tex.), cert. denied, 513 U.S. 1057, 115 S.Ct. 664, 130 L.Ed.2d 599 (1994).

We agree that the terms "law" and "regulation" evidence an intent to include common law claims. However, we stop short of concluding that common law claims are expressly preempted by the FBSA, because another provision in the Act pulls us away from that conclusion. As-the Lewises point out, Congress included a savings clause in the Act, which seems to save common law claims from preemption. That clause, which is found within the section of the Act entitled "Penalties and

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Injunctions," provides:

> Compliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law.

46 U. S. C. A. § 4311 (g) (West Supp. 1995).

[6][7] Because the FBSA preempts an area (safety) that historically has been regulated by the states through their police powers, we must construe the Act's preemption clause narrowly. See Medtronic, --- U.S. at 116 S.Ct. at 2250. The preemption clause easily could be read to cover common law claims, but because the savings clause indicates that at least some common law claims survive express preemption, we cannot give the preemption clause that broad reading. Instead, we must resolve doubts in favor of the narrower interpretation of the preemption clause and conclude that the express preemption clause does not cover common law claims. We hold that those claims are not expressly preempted.

The Lewises urge us to go further and hold that the savings clause demonstrates clear congressional intent to save common law claims from preemption. We find congressional ***1502** intent to be less than clear, given the conflicting language in the preemption and savings clauses. Just as the conflict between those provisions prevents us from concluding that the Lewises' claims are expressly preempted, so also does that conflict prevent us from concluding that those claims are expressly saved. See Taylor v. General Motors Corp., 875 F.2d 816, 825 (11th Cir.1989) (interpreting the National Traffic and Motor Vehicle Safety Act). The express terms of the FBSA simply fail to answer the question of whether Congress intended to preempt common law claims. As a result, our decision about preemption depends on whether the Lewises' claims are impliedly preempted by federal law. See id. at 827-28.

VIII. IMPLIED CONFLICT PREEMPTION

[8] The Lewises' claims are preempted impliedly by the FBSA to the extent that those claims conflict with the "accomplishment and execution of the full purposes and objectives of Congress." See

Freightliner Corp. v. Myrick, 514 U.S. 280 - ----115 S.Ct. 1483, 1487, 131 L.Ed.2d 385 (1995). In other words, the Lewises' claims are preempted if

they prevent or hinder the FBSA from operating the way Congress intended it to operate. In deciding whether the Lewises' claims conflict with the purposes of the FBSA, we do not apply a presumption against preemption, even though common law tort claims are a mechanism of the police powers of the state. Taylor, 875 F.2d at 826. "Under the Supremacy Clause of the Federal Constitution, '[t]he relative importance to the State of its own law is not material when there is a conflict with a valid federal law,' for 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.' " Felder v. Casey, 487 U.S. 131, 138, 108 S.Ct. 2302, 2307, 101 L.Ed.2d 123 (1988) (citations omitted).

According to Brunswick, the Lewises' claims are preempted by implication because those claims would interfere with the regulatory scheme enacted by Congress in the FBSA. Brunswick argues that the Coast Guard has the last say on whether a safety feature on boats or associated equipment should be required. Where the Coast Guard believes that a safety feature should not be required, Brunswick argues that states may not require the feature, even through common law claims.

[9][10] "[A] federal decision to forgo regulation in a given area may imply an authoritative federal determination that the area is best left unregulated, and in that event would have as much preemptive force as a decision to regulate." Arkansas Elec. Cooperative Corp. v. Arkansas Pub. Serv. Comm'n, 461 U.S. 375, **384, 103 S.Ct. 1905, 1912,** 76 L.Ed.2d 1 (1983) (emphasis in original). Though a decision not to regulate does not always have preemptive effect, see Puerto Rico Dept. of Consumer Affairs v. Isla Petroleum Corp., 485 U.S. 495, 503, 108 S.Ct. 1350, 1355, 99 L.Ed.2d 582 (1988), it does "where [the] failure of ... federal officials affirmatively to exercise

their full authority takes on the character of a ruling that no such regulation is appropriate or approved pursuant to the policy of the statute." Ray v. Atlantic Richfield Co., 435 U.S. 151, 178, **98 S.Ct. 988,** 1004, 55 L.Ed.2d 179 (1978) (citations omitted).

[111 The Lewises argue that the rule of Atlantic Richfield does not apply here, because Congress did not intend for a mere decision not to regulate to have preemptive effect under the FBSA. In the

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Lewises' view, any state regulation on boat and equipment safety standards is permissible, unless the Coast Guard promulgates a regulation that conflicts with the state regulation. As the Lewises understand the FBSA regulatory scheme, a Coast Guard position not to impose a safety standard on a matter leaves room for states to impose safety standards on ,that matter. There being no regulation on propeller guards, the Lewises argue that their claims are not affected by the Coast Guard's position. For support, they point to Freightliner Corp. v. Myrick, 514 U.S. 280, ***1503** 115 S.Ct. 1483, 131 L.Ed.2d 385 (1995), a case in which the Supreme Court concluded that an absence of regulation on a safety matter did not preempt state common law claims imposing such standards.

In Freightliner, the Supreme Court considered whether common law claims based on the failure to install antilock brakes were expressly or impliedly preempted by the Vehicle Safety Act. See id. at ---, 115 S.Ct. at 1485. The preemption clause in the Vehicle Safety Act provided:

> Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle

equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.

15 U.S.C.A. § 1392(d) (West 1982) (repealed 1994). The defendants in Freightliner argued that the failure-to-install claims were preempted, because the relevant agency had indicated its intent to regulate braking systems by promulgating a regulation on that matter. That regulation was struck down by an appellate court, but the defendants in Freightliner believed it still had preemptive effect, because it demonstrated the agency's intent to forbid state regulation on braking systems. Id. at 115 S.Ct. at 1487.

The Supreme Court rejected that argument. First, the Court explained, there was no evidence that the Vehicle Safety Act gave the relevant federal agency exclusive authority to issue safety standards. Id. In fact, the preemption clause in that act clearly implied that states could impose safety standards on auto manufacturers, until the federal government came forward with a different standard. Therefore,

under the Vehicle Safety Act regulatory scheme, the absence of regulation failed to have preemptive effect under the Atlantic Richfield doctrine; instead, the agency's failure to put into effect a valid regulation left the state common law intact. Id. Furthermore, the Court reasoned, Atlantic Richfield was inapposite because:

the lack of federal regulation [on antilock brakes] did not result from an affirmative decision of agency officials to refrain from regulating air brakes. [The agency] did not decide that the minimum, objective safety standard required by 15 U.S.C. § 1392(a) should be the absence of all standards, both federal and state.

Id. (footnote omitted).

In contrast to the Vehicle Safety **Act, the FBSA** was intended to give its regulatory agency--the Coast Guard--exclusive authority to

issue safety standards: This section [containing the preemption clause] provides for federal preemption in the issuance of boat and equipment safety standards. This conforms to the long history of preemption in maritime safety matters and is founded on the need for uniformity applicable to vessels moving in interstate commerce. In this case it also assures that manufacture for the domestic trade will not involve compliance with widely varying local requirements. At the same time, it was recognized that there may be serious hazards which are unique to a particular locale and which would justify variances at least with regard to the carriage or use of marine safety articles on boats. Therefore, the section does permit individual States to impose requirements with respect to carrying or using marine safety articles which go beyond the federal requirements when necessary to meet uniquely hazardous local conditions or circumstances. A right of disapproval, however, is **reserved to the** Secretary to insure that indiscriminate use of state authority does not seriously impinge on the basic need for uniformity.

> The section does not preempt state law or regulation directed at safe boat operation and use, which was felt to be appropriately within the purview of state or local concern.

S. Rep. No. 92-248, reprinted in 1971 U.S.C.C.A.N. at 1341. See Elliott v. Brunswick *1504 Corp., 903 F.2d 1505, 1508 (11th Cir.1990) ("[T]he [FBSA] gives the Coast Guard the exclusive responsibility for establishing safety regulations.") (dicta); Williams v. U.S. Dept. of Transportation,

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781 F.2d 1573, 1577 & n. 4 (1 Ith Cir. 1986) (with the FBSA Congress expressly preempted state regulation regarding performance and safety standards for boats and associated equipment) (dicta). While an absence of regulation under the Vehicle Safety Act does not prevent states from regulating motor vehicle

safety standards, an ,absence of federal regulation under the FBSA means that no regulation, state or federal, is appropriate. Freightliner is distinguishable for that reason.

Also in contrast to Freightliner, the relevant agency here, the Coast Guard, did make an affirmative decision to refrain from regulating propeller guards. Unlike the agency in Freightliner, the Coast Guard did not try to promulgate a regulation, and then fail, under a statutory scheme that would leave state law intact in the absence of federal regulatory action. Instead, under a statutory scheme that forbids any state standard or regulation "not identical to" a federal regulation, the Coast Guard decided not to issue a regulation. After consulting with the Advisory Council and reviewing the available data, the Coast Guard reached a carefully considered decision that "[alvailable propeller guard accident data do not support imposition of a regulation requiring propeller guards on motorboats."

The Coast Guard decided not only that a federal regulation would be inappropriate, but that the scientific data counseled against any regulation requiring propeller guards. Given that Congress intended for the FBSA to create a uniform system of regulation, and that the Coast Guard has determined that propeller guards should not be required, the Coast Guard's position mandates an absence of both federal and state propeller guard requirements. See Ryan v. Brunswick Corp., 454 Mich. 20, 557 N.W.2d 541, 549-50 (1997). See also Puerto Rico, 485 U.S. at 503, 108 S.Ct. at 1355 ("Where a comprehensive federal scheme intentionally leaves a portion of the regulated field without controls, then the preemptive inference can be drawn--not from federal inaction alone, but from inaction joined with action. ") (emphasis in original). Freightliner does not require that we hold otherwise.

But the Lewises contend that even if Freightliner is not controlling here, we cannot find an implied conflict between their claims and the Act, because we know from the savings clause that Congress expected some common law claims to be brought in

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this area. About the savings clause, the Senate report says:

This section is a Committee amendment and is intended to clarify that compliance with the Act or standards, regulations, or orders promulgated thereunder, does not relieve any person from liability at common law or under State law. The purpose of the section is to assure that in a product liability suit mere compliance by a manufacturer with the minimum standards promulgated under the Act will not be a complete defense to liability. Of course, depending on the rules of evidence of the particular judicial forum, such compliance may or may not be admissible for its evidentiary value. S.Rep. No. 92-248, reprinted in 1971 U.S.C.C.A.N. at 1352.

[121 From the savings clause, we know that Congress understood at least some product liability claims to be consistent with the FBSA regulatory scheme. In order to decide which claims, we must determine when product liability claims can be brought without upsetting the overall scheme Congress intended. Addressing that question, several courts have held that the only claims which do not present a conflict with the FBSA regulatory scheme are product liability claims based on the defective design or installation of products that are already installed, as opposed to claims based on the failure to install a certain safety device. See Carstensen v. Brunswick Corp., 49 F.3d 430, 432 (8th Cir.), cert. denied, --- U.S - ----- 116 S.Ct. 182, 133 L.Ed.2d 120 (1995); **Moss *1505 v. Outboard Marine** Corp., 915 F.Supp. 183, 187 (E.D.Cal.1996); Mowery v. Mercury Marine, 773 F.Supp. 1012, 1017 (N.D.Ohio 1991); Rubin v. Brutus Corp., 487 So.2d 360, 363 (Fla. Dist. Ct. App. 1986); Farner v. Brunswick Corp., 239 III.App.3d 885, 180 III.Dec. 493, 498, 607 N.E.2d 562, 567 (1992); Ryan v. Brunswick Corp., 209 Mich.App. 519, 531 N.W.2d 793, 796 n. 1 (1995), aff'd, 454 Mich. 20, 557 N.W.2d 541 (1997); Mulhem v. Outboard Marine Corp., 146 **Wis.2d 604, 432 N.W.2d 130, 134-35** (1988). Permitting product liability claims against manufacturers for negligent or defective design of products required by the Coast Guard, or for products

provided voluntarily by manufacturers, simply requires manufacturers to comply with **FBSA** regulations, and to do any additional manufacturing, in a non-negligent and non-defective manner. Permitting such claims is consistent with the **FBSA** scheme, which is designed to ensure that boats and

associated equipment are safe. .

By contrast, claims based on the failure to install a product that the Coast Guard has decided should not be required would conflict with the regulatory uniformity purpose of the FBSA. Without doubt, the Lewises' product liability claims seek to impose -a propeller guard requirement. See Carstensen, 49 F.3d at 432. That requirement conflicts with the FBSA's grant of exclusive regulatory authority to the Coast Guard, and for that reason those claims are in conflict with and are therefore preempted by the Act.

[13] The Lewises argue that their fraud claim should be treated differently from their other claims, because it - would not create a propeller guard requirement beyond FBSA requirements. We disagree. If the Lewises succeeded with their fraud claim, a jury could impose liability upon Brunswick for attempting to persuade the Coast Guard and others that propeller guards are unsafe. The necessary element of causation in any such claim would be that but for the wrongful conduct of Brunswick, propeller guards would have been required by the Coast Guard. Such a judgment would conflict with the Coast Guard's position that propeller guards should not be required. Thus, the fraud claim is impliedly preempted by the Coast Guard's position and the preemptive effect given that position by the FBSA.

Regulatory fraud claims of this nature are impliedly preempted for fundamental, systemic reasons. Permitting such claims would allow juries to secondguess federal agency regulators through the guise of

punishing those whose actions are deemed to have interfered with the proper functioning of the regulatory process. If that were permitted, federal regulatory decisions that Congress intended to be dispositive would merely be the first round of decision making, with later more important rounds to be played out in the various state courts. Virtually any federal agency decision that stood in the way of a lawsuit could be challenged indirectly by a claim that the industry involved had

misrepresented the relevant data or had otherwise managed to skew the regulatory result. Ironically, such circumvention of the regulatory scheme likely would be more pronounced where, as here, Congress mandated more extensive industry input into the regulatory process. See 46 U.S.C. § 4302(c). Congress could not have intended for the process it so carefully put in place to be so easily and thoroughly undermined. IFNI]

FNI. The Lewises' claim may be read to address alleged fraudulent misrepresentations by Brunswick to individuals and groups outside the federal government. To the extent that the Lewises intend to hold Brunswick liable for allegedly dissuading other manufacturers from installing propeller guards, their claim fails on causation grounds, because their daughter was struck by a propeller on a Brunswick motor. To the extent that the Lewises seek to hold Brunswick liable for alleged fraud upon state regulators, their fraud claim is preempted because state regulatory decisions of the propeller guard issue are themselves preempted.

In sum, we conclude that because Congress has made the Coast Guard the exclusive authority in the area of boat and equipment safety standards, its position rejecting a propeller guard requirement takes on the character of a ruling that no such requirement may be imposed. That position impliedly *1506 preempts state law requirements of propeller guards, even in the form of common law claims. It also prevents plaintiffs from bringing fraud claims intended to demonstrate that the Coast Guard would have reached a

different conclusion on the matter of propeller guards but for alleged industry manipulation or subversion of the federal regulatory process. We hold that each of the Lewises' claims is preempted by implication because it conflicts with the Coast Guard's position on propeller guards and would interfere with the FBSA regulatory process designed by Congress.

IX. CONCLUSION

The district court's grant of summary judgment to Brunswick is AFFIRMED.

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APPENDIX D

WESTLAW BULLETIN

WESTLAW BULLETIN
U.S. Supreme Court
July 30, 1998

Products Liability: Implied Preemption of State Law Claims Against Outboard Engine Manufacturer -Certiorari Dismissed

The United States Supreme Court has dismissed, pursuant to Rule 46.1, a writ of certiorari that was previously granted from an Eleventh Circuit decision holding that the Federal Boat Safety Act impliedly preempted state law negligence and products liability claims against an outboard engine manufacture premised on the failure to provide a propeller guard. Rule 46.1 provides for dismissal upon the agreement of the parties. The Eleventh Circuit had stated that because Congress has made the Coast Guard the exclusive authority in the a ~ of boat and equipment safety standards, the position of the Coast Guard rejecting a propeller guard requirement took on the character of a ruling that no such requirement may be imposed. That position impliedly preempted state law requirements of propeller guards, said the Eleventh Circuit, even in the form of common-law state tort claims. Further, continued the Eleventh Circuit, the Coast Guard's position prevented the plaintiffs from bringing fraud claims against the manufacturer that were intended to demonstrate that the Coast Guard would have reached a different conclusion in the matter of propeller guards but for misrepresentations by the manufacturer concerning the performance differences between guarded engines and unguarded engines.

The petition for certiorari presented two questions. The first question was whether, in light of recent Supreme Court holdings on preemption, it is constitutionally permissible to imply the federal

preemption of state common law claims into the Act, which has both an express preemption clause and an express "savings clause" in respect to state authority, when the Act expressly p- tides a reliable indicium of congressional intent with respect to state authority, and when no federal agency has issued an applicable preemption Ivregulation" as expressly required by the Act. The second question asked whether it was error to hold that torts of omission are impliedly preempted under the Act while torts of commission are simultaneously expressly safe from preemption, when such a differentiation between types of torts is not made in the Act's preemption or "savings" clauses. (Case below: Lewis v. Brunswick Corp., 107 F.3d 1494 (C.A.11-Ga. 1997).)

The Eleventh Circuit's decision may be viewed by using FIND with the citatior 107 F.3d 1494.

Lewis v. Brunswick Corp.
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APPENDIX E

AMICUS CURIE BRIEF OF SOLICITOR GENERAL

CORDS
AND
RIEFS

No. 97-288

DEC 29 1997

CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1997

VICKY LEWIS, ET UX., INDIVIDUALLY, AS PARENTS, AS NEXT FRIENDS AND AS ADMINISTRATORS OF THE ESTATE OF KATHRYN C. LEWIS, DECEASED,
PETITIONERS

v.

BRUNSWICK CORPORATION

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

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QUESTION PRESENTED

Whether petitioners' state common law tort action, based on the respondent's failure to install a propeller guard on a motorboat, is preempted by the Federal Boat Safety Act of 1971, 46 U.S.C. 4306, or by the decision of the Secretary of Transportation to take no regulatory action to require the installation of propeller guards on recreational boats.

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In the Supreme Court of the United States

OCTOBER TERM, 1997

No. 97-288

VICKY LEWIS, ET UX., INDIVIDUALLY, AS PARENTS, AS NEXT FRIENDS AND AS ADMINISTRATORS OF THE ESTATE OF KATHRYN C. LEWIS, DECEASED, PETITIONERS

v.

BRUNSWICK CORPORATION

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

INTEREST OF THE UNITED STATES

The Federal Boat Safety Act of 1971, 46 U.S.C. 4301-4311, authorizes the Secretary of Transportation to promulgate appropriate federal safety standards for recreational boats. 46 U.S.C. 4302(a). This case concerns the preemptive effect of the Secretary's decision not to take any regulatory action requiring boat manufacturers to install propeller guards on motorboats. The Court's decision may have a substantial effect on the manner in which the Secretary exercises his regulatory authority under the Act.

STATEMENT

1. a. For much of this century, Congress has imposed statutory requirements to promote motorboat safety. In 1910, for example, Congress enacted a requirement that

motorboats of specified sizes carry lights and safety equipment. See Act of June 9, 1910, ch. 268, §§ 2-6, 36 Stat. 462-463. The purpose of that law was to "prevent[] collisions of vessels and to regulate equipment of certain motor boats on the navigable waters of the United States." H.R. Rep. No. 1162, 61st Cong., 2d Sess. 1 (1910). A law passed in 1918 required motorboats to be numbered, in part to facilitate enforcement of the safety requirements imposed by the 1910 statute. See Act of June 7, 1918, ch. 93, 40 Stat. 602; see also H.R. Rep. No. 361, 65th Cong., 2d Sess. 1 (1918).

In 1940, Congress promulgated a major overhaul of the existing requirements concerning motorboats. See Act of Apr. 25, 1940, ch. 155, 54 Stat. 163. The principal purposes of that law were to expand the definition of "motorboat," to provide for local inspectors to ensure compliance with equipment and design requirements, and to impose penalties on persons who operated motorboats in a reckless or negligent manner. *Ibid.*; see also S. Rep. No. 676, 76th Cong., 1st Sess. (1939). In 1958, Congress enacted further boat numbering requirements and declared it "to be the policy of Congress to encourage uniformity of boating laws, rules, and regulations as among the several States and the Federal Government to the fullest extent practicable, subject to reasonable exceptions arising out of local conditions." Federal Boating Act of 1958, Pub. L. No. 85-911, § 9, 72 Stat. 1757. Because that law contemplated a system of state numbering of vessels, it had to address the coordination of jurisdiction between States and the Federal Government. Congress provided that "[n]othing herein shall interfere with, abrogate or limit the jurisdiction of any State" with respect to its numbering system. *Id.* § 13(4), 72 Stat. 1758. The Department of Treasury's

comments on the proposed legislation reflect agreement with that scheme:

> The relinquishment by the Federal Government to the States of a portion of its traditional control of motorboating appears to be a logical and healthy approach to the partial solution of the vast problem of recreational boating safety. The magnitude and complexity of adequate control and the encouraging response of State governments dictate coordination and continuing cooperation between sovereign governments in this field.

S. Rep. No. 2340, 85th Cong., 2d Sess. 5 (1958).

By the early 1970s, approximately 40 million Americans were engaging in recreational boating activities each year in approximately 9 million boats. S. Rep. No. 248, 92d Cong., 1st Sess. 6 (1971).[1] That widespread participation came at a cost, as nearly 7,000 persons lost their lives in boating accidents during the period 1966-1970. *Id.* at 7. In response to those developments, Congress enacted the Federal Boat Safety Act (FBSA) in 1971 "to provide a coordinated national boating safety program involving both the Federal Government and the States * * * [in] a single comprehensive Act dealing with the subject of safety for boats used principally for other than commercial use." *Id.* at 6. Congress intended "to improve boating safety by requiring manufacturers to provide safer boats and boating equipment to the public through compliance with safety standards to be promulgated by the Secretary of the Department in which the Coast Guard is

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[1] The number of registered recreational boats in the United States today is approximately 12 million. National Association of State Boating Law Administrators, *Reference Guide to State Boating Laws* 6 (Ron Sarver & Chris Moore, eds., 2d ed. 1997).

operating—presently the Secretary of Transportation." *Ibid.*

Congress further declared "the purpose of this Act to improve boating safety * * * by encouraging and assisting participation by the several States, the boating industry, and the boating public in [the] development of more comprehensive boating safety programs; by authorizing the establishment of national construction and performance standards for boats and associated equipment; and by creating more flexible regulatory authority concerning the use of boats and equipment." Pub. L. No. 92-75, § 2, 85 Stat. 213-214.[2] Congress also sought "to encourage greater and continuing uniformity of boating laws and regulations as among the several States and the Federal Government, a higher degree of reciprocity and comity among the several jurisdictions, and closer cooperation and assistance between the Federal Government and the several States in developing, administering, and enforcing Federal and State laws and regulations pertaining to boating safety." *Id.* at 214.

To accomplish those goals, the Act authorizes the Secretary of Transportation to prescribe regulations estab-

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[2] The Senate report states: "The need for uniformity in standards if interstate commerce is not to be unduly impeded supports the establishment of uniform construction and equipment standards at the Federal level." S. Rep. No. 248, *supra*, at 14. A number of government witnesses in support of the Act emphasized the need for uniform federal construction and equipment standards. See, *e.g.*, *National Boating Safety Program: Hearing on S. 696 Before the Merchant Marine Subcomm. of the Senate Comm. on Commerce*, 92d Cong., 1st Sess. 50 (1971) (Admiral Chester R. Bender, Commandant of the Coast Guard); *id.* at 70 (John H. Reed, Chairman, National Transportation Safety Board); *Recreational Boat Safety: Hearings on H.R. 15041, 15140 Before the Subcomm. on Coast Guard, Coast and Geodetic Survey, and Navigation of the House Comm. on Merchant Marine & Fisheries*, 91st Cong., 2d Sess. 66 (1970).

lishing minimum safety standards for recreational boats and associated equipment. See 46 U.S.C. 4302. The Secretary has delegated that rulemaking authority to the Coast Guard. See 49 C.F.R. 1.46(n)(1). In promulgating regulations, the Coast Guard must consider the extent to which the regulations will contribute to recreational vessel safety. 46 U.S.C. 4302(c)(1) and (2). The Coast Guard may not establish regulations compelling substantial alterations of existing boats and associated equipment unless compliance would "avoid a substantial risk of personal injury to the public." 46 U.S.C. 4302(c)(3). Before promulgating a regulation, the Coast Guard must consult with the National Boating Safety Advisory Council (Advisory Council) on the need for regulation and must comply with the notice and comment provision of the Administrative Procedure Act, 5 U.S.C. 553. 46 U.S.C. 4302(c)(4); see S. Rep. No. 248, *supra*, at 19.[3]

b. The question presented by this case is whether the Coast Guard's decision *not* to promulgate a regulation requiring manufacturers to install propeller guards on recreational motorboats preempts a state common law damages action premised on an allegedly negligent failure

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[3] The Coast Guard has promulgated numerous regulations regarding boat safety, specifying equipment to be carried on boats, and mandating design standards for minimum safety requirements. Those regulations address a range of different topics, including: vessel numbering and accident reporting, see 33 C.F.R. Pts. 173, 174; requirements for safety equipment to be carried on boats, such as personal flotation and visual distress signal devices, see *id.* Pt. 175; measures to correct especially hazardous conditions, *id.* Pt. 177; defect notification requirements, *id.* Pt. 179; requirements for manufacturers concerning certifications of compliance, identification of boats, and instructions for personal flotation devices, *id.* Pt. 181; requirements regarding safe boat capacity and flotation devices, and standards for horsepower, electrical, fuel, ventilation, and start-in-gear systems, *id.* Pt. 183; and vessel identification requirements, *id.* Pt. 187.

by the manufacturer to install such a guard. In 1988, the Coast Guard directed the Advisory Council to examine the feasibility and safety advantages and disadvantages of requiring propeller guards on recreational boats.[4] The Advisory Council appointed a Propeller Guard Subcommittee for that purpose. After an extensive review of scientific data and testimony, the Subcommittee determined that the incidence of injuries or fatalities caused by persons coming into contact with propellers was relatively small. See J.A. 92. The Subcommittee also found that propeller guards adversely affect the operation of boats at certain speeds and that such devices could create additional and more severe hazards. See J.A. 69-71. The Subcommittee further concluded:

> Since there are hundreds of propulsion unit models now in existence, and thousands of hull designs, the possible hull/propulsion unit combinations are extremely high. No simple universal design suitable for all boats and motors in existence has been described or demonstrated to be technologically or economically feasible. To retrofit the some 10 to 15,000,000 existing boats would thus require a vast number of guard models at prohibitive cost.

J.A. 71. Therefore, it recommended that the Coast Guard "should take no regulatory action to require propeller guards." J.A. 73.

The Advisory Council accepted the report and adopted its recommendations. See Pet. App. A8. The Coast Guard,

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[4] The Advisory Council must consist of 21 members, equally divided among representatives of "State officials responsible for State boating safety programs," "recreational vessel manufacturers and associated equipment manufacturers," and "national recreational boating organizations and * * * the general public." 46 U.S.C. 13110(b)(1)(A)-(C).

in turn, also accepted the report's recommendations. J.A. 163-167. In a letter to the Advisory Council agreeing with its recommendation that the Coast Guard "should take no regulatory action to require propeller guards," the Coast Guard Chief of the Office of Navigation Safety and Waterway Services wrote:

> The regulatory process is very structured and stringent regarding justification. Available propeller guard accident data do not support imposition of a regulation requiring propeller guards on motorboats. Regulatory action is also limited by the many questions about whether a universally acceptable propeller guard is available or technically feasible in all modes of boat operation. Additionally, the question of retrofitting millions of boats would certainly be a major economic consideration.
>
> The Coast Guard will continue to collect and analyze accident data for changes and trends; and will promote increased/improved accident reporting as addressed in recommendation 2. The Coast Guard will also review and retain any information made available regarding development and testing of new propeller guarding devices or other information on the state of the art.

Letter from Robert T. Nelson, Rear Admiral, U.S. Coast Guard, Office of Navigation, Safety and Waterway Services to A. Newell Garden, Chairman, National Boating Safety Advisory Council 1 (Feb. 1, 1990) (Coast Guard Letter), J.A. 163.

In recent years, the Coast Guard has continued to study various policy proposals to prevent propeller-related injuries. In 1995, for example, the Coast Guard issued an Advance Notice of Proposed Rulemaking (ANPRM) requesting comment on "the public's present feelings about the use of propeller guards or possible alternatives to

propeller guards on these vessels," a request occasioned by a serious accident involving a rented houseboat. 60 Fed. Reg. 25,191 (1995). In 1996, the Coast Guard issued an ANPRM "to gather current, specific, and accurate information about the injuries involving propeller strikes and rented boats." 61 Fed. Reg. 13,123 (1996). And, in 1997, the Coast Guard sought "comments on the effectiveness of specific devices and interventions which have been suggested for reducing the number of recreational boating accidents involving rented power boats in which individuals are injured by the propeller." 62 Fed. Reg. 22,991 (1997). Because it received few responses to that request, the Coast Guard extended the period for comments. See *id.* at 44,507. The Coast Guard has not issued any regulations to require or prohibit propeller guards in any vessels.

c. Two provisions of the FBSA speak to the preemption issue in this case. The preemption clause of 46 U.S.C. 4306 states that, unless permitted by the Secretary, "a State or political subdivision of a State may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment * * * that is not identical to a regulation prescribed [by the Coast Guard] under section 4302 of this title." The second pertinent provision, 46 U.S.C. 4311(g), is a savings clause. It states that "[c]ompliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law."[5]

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[5] Notwithstanding the existence of federal statutory requirements regarding certain aspects of motorboat safety, none of the congressional acts prior to the FBSA in 1971 contained either a preemption clause or a savings clause. See statutes cited at pages 1-3, *supra*.

2. Gary and Vicky Lewis sued respondent Brunswick Corporation in state court to recover damages for the death of their daughter, who died after she fell or was thrown from a boat and was then struck by a Brunswick engine propeller. Petitioners' complaint alleged that the Brunswick engine was defective because it lacked a propeller guard. See J.A. 6-9. Respondent removed the case to federal court on diversity grounds and moved for summary judgment. The district court held that the Lewises' claims are preempted by the FBSA, Pet. App. A31, and the Eleventh Circuit affirmed, *id.* at A1-A25.

The court of appeals rejected the contention that the Lewises' claims are expressly preempted. It stated that "the conflicting language in the preemption and savings clauses" prevented a finding that Congress clearly intended to preclude common law claims. Pet. App. A14. The court also held that this tension between the preemption clause and the savings clause prohibited a finding that Congress expressly intended to save those claims. *Ibid.* As a result, the court held that its decision about preemption depended on whether the Lewises' claims are impliedly preempted by federal law. *Id.* at A15.

In analyzing that question, the court sought to determine whether the Lewises' claims would "prevent or hinder the FBSA from operating the way Congress intended it to operate." Pet. App. A15. The court concluded that at the heart of the regulatory scheme established by the FBSA was Congress's decision to make the Coast Guard the "exclusive authority to issue safety standards." *Id.* at A18. That conclusion led the court to hold that "an absence of federal regulation under the FBSA means that no regulation, state or federal, is appropriate." *Id.* at A20. The court found distinguishable this Court's decision in *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 286 (1995), which held that the failure by the National Highway

Transportation Safety Administration (NHTSA) to promulgate a regulation on antilock brakes under the National Traffic and Motor Vehicle Safety Act of 1966 (NTMVSA), 15 U.S.C. 1381 *et seq.*, did not preempt state common law claims based on the failure to install such brakes on a tractor trailer truck. The court of appeals stated that the NTMVSA, in contrast to the FBSA, did not give the responsible federal agency (NHTSA) the exclusive authority to issue safety standards, but clearly allowed States to impose safety standards on auto manufacturers until the Federal Government came forward with a different standard. Pet. App. A18.

The court of appeals acknowledged that, "[f]rom the savings clause, we know that Congress understood at least some product liability claims to be consistent with the FBSA regulatory scheme." Pet. App. A21. But it decided that only "product liability claims against manufacturers for negligent or defective design of products required by the Coast Guard, or for products provided voluntarily by manufacturers," would be consistent with the FBSA scheme. *Id.* at A22. By contrast, the court found that "claims based on the failure to install a product that the Coast Guard has decided should not be required would conflict with the regulatory uniformity purpose of the FBSA." *Ibid.* Consequently, the court held, the Coast Guard's decision not to impose a propeller guard requirement "impliedly preempts state law requirements of propeller guards, even in the form of common law claims." *Id.* at A24.

SUMMARY OF ARGUMENT

The court of appeals correctly ruled that the express preemption provision in the Federal Boat Safety Act of 1971 (FBSA), 46 U.S.C. 4306, does not preempt petitioners' common law claims. As an initial matter, the Court need not resolve a broader ground of disagreement between the

parties: whether Section 4306 preempts state prescriptive regulations in the absence of a federal rule or regulation. This case involves not a state positive rule, but rather a common law damages action. Section 4306 contains four *textual indications* that Congress did not intend to foreclose such claims. First, as this Court has noted in a number of cases, courts should not infer that use of the word "law" in the preemption provision includes common law claims absent a clearer indication of that purpose by Congress. Second, the FBSA provides that only a "law or regulation" promulgated by a "State or political subdivision of a State" is subject to express preemption. A court in a common law damages action does not fall within the ordinary meaning of "State or political subdivision of a State" because state judicial officers do not petition the Secretary of a federal department for permission to proceed with a state lawsuit. That reading is consistent with the Coast Guard's practice since 1971 of working with state executive officials to determine whether state laws or regulations conflict with federal standards. Third, the Secretary's permissive authority to promulgate "minimum safety standards" (46 U.S.C. 4302(a)(1)) does not foreclose state tort law judgments that raise the manufacturer's standard of care above the federally required minimum. Finally, the savings clause of 46 U.S.C. 4311(g) *does* expressly contain an intent to preserve "common law" claims. Inclusion of that language in the savings clause but not in the preemption provision further supports a reading that the preemption clause was not intended expressly to preempt state common law claims.

Although the court below correctly concluded that the preemption clause does not expressly preempt petitioners' claims, it erred in ruling that those claims are impliedly preempted by the statutory scheme. Since the Coast Guard concluded after extensive study that the available

data were insufficient to warrant imposition of a regulation regarding propeller guards, there is no federal standard with which a state common law action would conflict. Similarly, a common law tort claim does not defeat the purposes of the Act, since the Coast Guard can promulgate any regulation regarding propeller guards in the future, if the appropriate justifications exist.

ARGUMENT

PETITIONERS' CLAIMS ARE NOT PREEMPTED BY EITHER THE FEDERAL BOAT SAFETY ACT OR THE COAST GUARD'S DECISION NOT TO PROMULGATE A PROPELLER GUARD REGULATION

Under this Court's settled preemption jurisprudence, state law is preempted "in three circumstances":

> First, Congress can define explicitly the extent to which its enactments pre-empt state law. * * * Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. * * * Finally, state law is pre-empted to the extent that it actually conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

English v. *General Elec. Co.*, 496 U.S. 72, 78-79 (1990) (citations omitted). The court below correctly held that petitioners' claims are not expressly preempted by the Federal Boat Safety Act of 1971 (FBSA), but it erred in holding that those claims are impliedly preempted by the

Coast Guard's decision not to promulgate a regulation concerning propeller guards.

A. The Text Of The Act Does Not Support A Finding Of Express Preemption Of Petitioners' Common Law Claims

1. As with the interpretation of any statutory text, "analysis of the scope of the pre-emption statute must begin with its text." *Medtronic, Inc.* v. *Lohr*, 116 S. Ct. 2240, 2250 (1996). Indeed, although the existence of an express preemption clause does not negate the need for an analysis of implied preemption, see *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 288-289 (1995), "[i]f the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent," *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993).

The preemption clause at issue in this case, 43 U.S.C. 4306, provides:

> Unless permitted by the Secretary under section 4305 of this title, a State or political subdivision of a State may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment (except insofar as the State or political subdivision may, in the absence of the Secretary's disapproval, regulate the carrying or use of marine safety articles to meet uniquely hazardous conditions or circumstances within the State) that is not identical to a regulation prescribed under section 4302 of this title.

Section 4302, in turn, provides in pertinent part that "the Secretary *may* prescribe regulations establishing mini-

mum safety standards for recreational vessels and associated equipment." 46 U.S.C. 4302(a)(1) (emphasis added).

2. The preemption clause of Section 4306 is susceptible of at least two interpretations. One is that States cannot enact positive rules or regulations without the approval of the Secretary, regardless of whether a federal standard is in effect. That reading appears to be favored by respondent. See Br. in Opp. 20. It is supported by the introductory clause of the section, which provides that, "[u]nless permitted by the Secretary under section 4305 of this title, a State or political subdivision of a State may not establish * * * a law or regulation establishing a[n] * * * equipment performance * * * standard." 46 U.S.C. 4306. The legislative history provides further support for that interpretation. The Senate Report states: "This section provides for federal preemption in the issuance of boat and equipment safety standards. This conforms to the long history of preemption in maritime safety matters and is founded on the need for uniformity applicable to vessels moving in interstate commerce. In this case it also assures that manufacture for the domestic trade will not involve compliance with widely varying local requirements." S. Rep. No. 248, *supra*, at 20.[6]

The Coast Guard has long interpreted the provision to preempt state positive laws and regulations, even when there is no counterpart federal regulation in effect under the Act. The day after the FBSA was enacted, the Secretary of Transportation issued a statement exempting all

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[6] The House report, which accompanied a bill that did not contain a savings provision, went even further in describing the preemptive effect of the proposed legislation: "The bill preempts the field on boating standards or regulations. Subject to review by the Secretary, however, States may require certain marine articles to meet uniquely hazardous situations in their States." H.R. Rep. No. 324, 92d Cong., 1st Sess. 11 (1971); see also *id.* at 15-16.

existing state laws from preemption under Sections 9 and 10 of the FBSA. The Secretary explained that "[b]oating safety will not be adversely affected by continuing in effect those existing laws and regulations of the various States and political subdivisions until new boating safety regulations are issued under the Federal Boat Safety Act of 1971." Department of Transportation, Office of the Secretary, Exemption [from Section 10 of the Federal Boat Safety Act] to Preserve Certain State and Local Boat Safety Laws and Regulations, August 11, 1971. See 36 Fed. Reg. 15,764, 15,765 (1971). The Secretary further explained that "[t]his exemption applies only to laws and regulations in effect on the effective date of the Federal Boat Safety Act of 1971 and remains in effect until expressly superseded, revoked, or otherwise terminated." *Ibid.* Two years later, after issuing regulations pertaining to "Manufacturer Requirements" and "Boats and Associated Equipment," the Coast Guard superseded the 1971 general exemption from preemption with a more limited exemption that had the effect of preempting a range of previously exempted state statutes and regulations. See 38 Fed. Reg. 71, 6914 (1973). Subsequent correspondence from the Coast Guard has been consistent with the view that the FBSA preempts state-promulgated rules and regulations regardless of whether a federal standard is in existence.[7]

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[7] See, *e.g.*, J.A. 37-38 (letter from Coast Guard to New York Commissioner of Parks and Recreation regarding federal preemption of associated equipment requirements imposed by state navigation law); J.A. 39-40 (internal Coast Guard memorandum regarding comparison of state boating law equipment standards for preemption purposes); J.A. 41-43 (letter from Coast Guard to Illinois Department of Conservation regarding preemption of state fire extinguisher regulations). See also pages 19-20, *infra* (discussing kill switches).

A second possible interpretation of Section 4306 would permit state regulations to exist in the absence of a federal standard, on a reading that focused on the last clause of Section 4306: that a State may not establish a regulation "that is not identical to a regulation prescribed under section 4302 of this title." 46 U.S.C. 4306. Petitioners espouse that reading of the statute. See Pet. 9. Under that interpretation, a federal regulation would have to be in effect before a state law could be preempted by Section 4306.[8] The Coast Guard has not issued formal regulations requiring or prohibiting propeller guards within the meaning of Section 4302. On the contrary, as we have explained, in 1990 the Coast Guard specifically

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[8] In advancing that interpretation, petitioners rely on this Court's decision in *Freightliner*, which held that the absence of a federal regulation served as no preemptive bar to a state common law damages action. The preemption clause in the National Traffic and Motor Vehicle Safety Act of 1966 (NTMVSA) considered by this Court in *Freightliner*, however, is different from the one at issue here. The NTMVSA preemption clause provided: "Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment[,] any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard." 15 U.S.C. 1392(d) (1988). The FBSA premption clause, by contrast, provides that, "[u]nless permitted by the Secretary * * *, a State * * * may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment * * * that is not identical to a regulation prescribed under section 4302 of this title." 46 U.S.C. 4306. The Court based its decision in *Freightliner* on the introductory clause of the preemption provision, which required, as a prerequisite for preemption, that a federal regulation be "in effect" for the same aspect of performance. See 514 U.S. at 286. The FBSA's introductory clause is not written in a comparably limiting manner.

declined to institute rulemaking proceedings to require propeller guards. Accordingly, under petitioners' interpretation, the absence of a federal regulation concerning propeller guards is sufficient to save their claims from preemption under Section 4306.

3. The Court need not express an opinion as between those two readings of the express preemption provision. Even under the Coast Guard's longstanding interpretation of the preemption clause as discussed above, petitioners' common law claims are not preempted by Section 4306. That is so because this case does not concern any prescriptive state regulations, and the court of appeals' conclusion that a common law claim is not expressly preempted draws support from the text of Section 4306 itself and from the text and structure of the Act as a whole.

First, a judicial ruling in a tort action is not "a law or regulation establishing a recreational vessel * * * performance or other safety standard or imposing a requirement for associated equipment." As the plurality noted in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), "the presumption against pre-emption might give good reason to construe the phrase 'state law' in a pre-emption provision more narrowly than an identical phrase in another context." *Id.* at 522 (opinion of Stevens, J.). Moreover, as we argued in *Freightliner* with respect to similar language, a "standard" "would not ordinarily be thought to include duties of care that derive from the process of common law adjudication." U.S. Amicus Br. at 13 (No. 94-286). For example, a duty of care established in one tort suit with respect to one vessel and its associated propulsion system might or might not translate into a duty of care with respect to a different boat used in different circumstances. The term "standard" in Section 4306, therefore, is best understood to refer to a more definite gauge prescribed in advance by legislative or

administrative authorities. That understanding is further supported by use of the term "standard" in the FBSA to describe the regulations issued by the Secretary, which are prescriptive in nature and do not encompass common law liability. See 46 U.S.C. 4302. See also *Webster's Third New International Dictionary* 2223 (1986) (defining "standard"; def. 3a: "something that is established by authority, custom, or general consent as a model or example to be followed"; def. 7b: "carefully drawn specifications covering manufacturing material or equipment").[9]

Second, a court in a common law damages action would not normally be thought of as a "State or political subdivision of a State" within the meaning of Section 4306. Properly read, the preemption clause requires executive officers of the State or political subdivision to apply to the Secretary for permission to "establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other

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[9] The reference to "requirement" in the preemption clause does not change the analysis in the text. Although this Court in *Cipollone* found preemption of common law claims in a statute that used the word "requirements," the statutory language there was much broader. In that case the statute preempted "requirement[s] or prohibition[s] . . . imposed under State law." 505 U.S. at 520. While "state law" is broad enough to encompass state common law applied in tort actions, Section 4306 refers to "*a* law or regulation * * * *imposing* a requirement" (emphasis added), which is more naturally read to refer only to state positive law imposing prescriptive requirements that are similar to the "standards" that are also mentioned in Section 4302. Furthermore, the "requirement" in *Cipollone* involved "obligations 'with respect to the advertising or promotion' of cigarettes," *ibid.*, a more general and sweeping set of conditions on tobacco companies than a finding of liability would be with respect to a particular boat equipped with a particular propeller-driven propulsion system. Another distinction between the FBSA and the statutes at issue in *Cipollone* and *Medtronic* is that those statutes did not contain savings clauses expressly preserving common law claims.

safety standard." Absent much clearer textual language, it would be anomalous to compel state judicial officers to apply to the Secretary for authority to continue a damages action premised on a negligent design theory of liability. Extensive case law exists on a variety of theories alleging the negligent design of a boat. Except in cases involving propeller guards, the notion that federal standards (or the absence of standards, as the case may be) preempt common law design defect claims appears not to have been contemplated by courts and litigants.[10] The experience with

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[10] See, *e.g.*, *Detroit Marine Eng'g* v. *McRee*, 510 So. 2d 462 (Miss. 1987) (negligent design in boat steering device); *Rose* v. *Mercury Marine*, 483 So. 2d 1351 (Miss. 1986) (defective design of motor and boat states cause of action); *Young* v. *Tide Craft, Inc.*, 242 S.E.2d 671 (S.C. 1978) (assessing whether manufacturer's failure to install kill switch constituted defect); *Becker* v. *U.S. Marine Co.*, 943 P.2d 700 (Wash. App. 1997) (defective design of seating area in bow); *Dubecky* v. *S2 Yachts, Inc.*, 651 N.Y.S.2d 602 (App. Div. 1996) (defective design of cut-out transom and motor well of fishing boat); *Van Berkum* v. *Christian*, 530 N.E.2d 52 (Ill. App. 1988) (design defect claim of gear-shifting mechanism).

Prior to the Coast Guard's decision in 1990 not to promulgate a regulation concerning propeller guards, the idea that the absence of a federal standard on propeller guards might preempt state common law damages claims appears not to have been argued by litigants. See *Degen* v. *Bayman*, 241 N.W.2d 703 (S.D. 1976) (affirming award for plaintiff in propeller injury case). After the 1990 decision, boat manufacturers were sporadic in claiming preemption, although when they did, they typically prevailed with that argument. See, *e.g.*, *Ryan* v. *Brunswick Corp.*, 557 N.W.2d 541 (Mich. 1997) (finding preemption of claim predicated on failure to install propeller guard); *Beech* v. *Outboard Marine Corp.*, 584 So. 2d 447 (Ala. 1991) (preemption not discussed, but manufacturer prevailed on holding that failure to provide propeller guard fails to state cognizable claim); *Fitzpatrick* v. *Madonna*, 623 A.2d 322 (Pa. Super. Ct. 1993) (considering but rejecting claim of defective design in failure to install propeller guard); *Moss* v. *Outboard Marine Corp.*, 915 F. Supp. 183 (E.D. Cal. 1996) (finding

"kill switches" is instructive in showing the distinction between the ways the Coast Guard has viewed its power to preempt state positive law versus common law when it has not promulgated a regulation. Although the Coast Guard has exchanged correspondence with state officials to discourage the promulgation of a prescriptive state rule requiring kill switches on motorboats, it has not taken the position that common law claims predicated on a failure by manufacturers to install such devices are preempted by federal law.[11]

Third, 46 U.S.C. 4302(a) provides that the "Secretary may prescribe regulations establishing *minimum* safety standards" (emphasis added). The rationale for "specifying that performance rather than design requirements be adopted is to encourage manufacturers to compete freely in developing and selecting means of meeting or surpassing the performance standards." S. Rep. No. 248, *supra*, at 17. In view of the preemption clause voiding state rules and regulations that are not "identical" to federal stan-

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preemption of state common law claims under FBSA); *Davis* v. *Brunswick Corp.*, 854 F. Supp. 1574 (N.D. Ga. 1993) (same).

[11] A kill switch is a device that stops the throttle when the operator of the boat is thrown overboard. In 1979, the State of Alabama requested an exemption from the Coast Guard in order to impose a state regulation requiring a kill switch. In correspondence with the State, the Coast Guard explained that that request necessitated publication and opportunity for comment in the *Federal Register*. Alabama subsequently withdrew its request for an exemption. (That correspondence has been lodged with the Clerk and served upon counsel for the parties.) Contemporaneously with Alabama's request, there was litigation concerning kill switches in several state courts. See, *e.g.*, *Boatland of Houston, Inc.* v. *Bailey*, 609 S.W.2d 743 (Tex. 1980) (considering claim of defective design in failure to install kill switch but holding that evidence was sufficient to warrant verdict for defendant seller); *Young* v. *Tide Craft, Inc.*, 242 S.E.2d 671 (S.C. 1978) (holding that manufacturer's failure to install kill switch in boat did not constitute design defect).

dards, as well as the savings clause preserving state common law claims (discussed below), it is reasonable to infer that Congress intended the federal requirements to be a floor with respect to safety measures that manufacturers must adopt. In certain circumstances, tort liability may provide incentives for manufacturers to provide a higher standard of care than the "minimum safety standard" mandated by the Secretary in federal regulations.

Fourth, the preemptive scope of Section 4306 must be construed in light of the savings clause contained in 46 U.S.C. 4311(g), which provides: "Compliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law." As explained above, the words used in Section 4306, standing alone, do not appear to preempt common law actions. In addition, Congress's explicit recognition of "common law" claims in Section 4311(g)—and its omission of that phrase in Section 4306—further supports a reading of "law or regulation" in Section 4306 as not encompassing common law claims. See, *e.g.*, *City of Chicago* v. *Environmental Defense Fund*, 511 U.S. 328, 338 (1994) ("'[I]t is generally presumed that Congress acts intentionally and purposely' when it 'includes particular language in one section of a statute but omits it in another'") (quoting *Keene Corp.* v. *United States*, 508 U.S. 200, 208 (1993)).

Not only does the language of Section 4311(g) aid in the construction of Section 4306, but the savings clause also makes clear Congress's explicit intent to preserve tort liability. The Senate Report states that the savings clause was enacted "to assure that in a product liability suit mere compliance by a manufacturer with the minimum standards promulgated under the Act will not be a complete defense to liability." S. Rep. No. 248, *supra*, at

31-32.[12] A fortiori, where, as here, the Coast Guard has chosen not to promulgate a safety standard governing the relevant aspect of performance, the FBSA does not furnish "a complete defense to liability."

Nor does a reading of Sections 4306 and 4311(g) that permits common law claims in these circumstances undermine any purposes of the Act. The regulatory effect of a common law judgment is not as direct as that of positive enactments or prescriptions. See *English*, 496 U.S. at 85 (common law claims "neither direct nor substantial enough" to be within the preempted field); *Goodyear Atomic Corp.* v. *Miller*, 486 U.S. 174, 186 (1988) (noting that Congress may find the "incidental regulatory pressure" of state common law claims acceptable even if it concludes that direct state regulatory action is not); see also *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984) ("Congress intended * * * to tolerate whatever

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[12] The addition of the savings clause was a "Committee amendment" to the original bill. S. Rep. No. 248, *supra*, at 31. The language of the enacted savings provision closely tracks concerns expressed by Richard Schwartz, Executive Director, Boat Owners Association of the United States, who testified that:

> [W]e would recommend a savings provision with respect to the consumers' private remedies, which is not touched upon by the present Bill. We would like to see it explicitly clarified that compliance with standards issued under the Act does not relieve the manufacturer from liability under State or common law in private law suits. It should be made clear that this Act does not preempt state or common law. In addition, we would further state that the failure of the Secretary to promulgate a standard shall not be admissible in a private proceeding. This would preclude a manufacturer from utilizing against the consumer the lack of a standard as evidence of a safe condition.

National Boating Safety Program: Hearing on S. 696 Before the Merchant Marine Subcomm. of the Senate Comm. on Commerce, 92d Cong., 1st Sess. 88 (1971).

tension there was between [federal regulation and state common law claims, and] [w]e can do no less.").[13]

Any decision by manufacturers to respond to state tort liability for propeller-related injuries by placing a propeller guard on a boat will depend on a cost-benefit analysis of the risks associated with incurring liability in a personal injury case versus the costs and risks of putting propeller guards on boats.[14] With respect to certain models of boats used for particular purposes, such a weighing by the manufacturer may lead to the conclusion that the risks of incurring liability warrant no action. With respect to other products, the manufacturer may conclude that the risks justify a range of alternatives, including giving a prospective boat owner the option of installing a propeller guard, making that device a standard feature, or discontinuing propeller-driven propulsion systems altogether for certain types of boats.[15] Propeller-

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[13] In other circumstances, Congress has expressly ousted state common law claims where it has intended that result. See, *e.g.*, 17 U.S.C. 301(a) (preempting rights "under the common law or statutes of any State"); 29 U.S.C. 1144(c)(1) (preempting all state "laws, decisions, rules, regulations, or other State action having the effect of law").

[14] See, *e.g.*, Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. Legal Stud. 357, 358-359 (1984) (social utility of imposing regulations versus allowing tort liability to proceed "is assumed to equal the benefits parties derive from engaging in their activities, less the sum of the costs of precautions, the harms done, and the administrative expenses associated with the means of social control"); *United States* v. *Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947) (L. Hand, J.) (liability itself stems from a weighing of the probability of injury, the severity of injury, and "the burden of adequate precautions").

[15] As the record in this case makes clear, the Propeller Guard Subcommittee ascertained that "there are no indications that there is a generic or universal solution currently available or foreseeable in the future. The boating public must not be misled into thinking there is a 'safe' device which would eliminate or significantly reduce such injuries

strike injuries have involved a range of different boat types, from houseboats to miniboat racers.[16] Thus, a decision by a manufacturer to respond to a lawsuit charging negligence in the design of particular boats for particular uses stands in stark contrast to state prescriptive regulations that attempt to create uniformity in the manufacture of all propeller-driven vessels, or even with regard to all products within a certain sub-class of vessels.

4. The court of appeals held that the preemption provision of the FBSA does not preempt a state common law tort claim for defective product design because the savings provision of Section 4311(g) required it to "construe the Act's preemption clause narrowly." Pet. App. A14. The court observed that "[t]he preemption clause easily could be read to cover common law claims, but because the savings clause indicates that at least some common law claims survive express preemption, we cannot give the preemption clause that broad reading." *Ibid.* Yet in declining to construe the savings clause affirmatively to allow petitioners' claims to proceed, the court functionally read the express preemption clause and the express savings clause to cancel each other out, and chose to resolve this case on implied preemption grounds, based on a supposedly overriding policy of uniformity not expressly

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or fatalities." J.A. 136-137. A range of different propeller guards have been patented, however, and alternative propulsion systems such as water jet propulsion (the method used in jet skis) may provide suitable alternatives to certain types of existing propeller-driven boats. See J.A. 202-209.

[16] See, *e.g.*, 60 Fed. Reg. 25,191 (1995) (houseboat); *Seymour* v. *Brunswick Corp.*, 655 So. 2d 892 (Miss. 1995) (165-horsepower MerCruiser on 19-foot Glastron boat); *Calabro* v. *Outboard Marine Corp.*, 599 So. 2d 717 (Fla. Ct. App. 1992) (miniboat); *Veal* v. *Teleflex, Inc.*, 586 So. 2d 188 (Ala. 1991) (bass fishing boat); *Beech*, 584 So. 2d at 447 (85-horsepower Johnson boat engine); *Degen*, 241 N.W.2d at 705 (210-horsepower Outboard Marine engine).

mandated by the text of the Act. Our reading of the express preemption and savings provisions, by contrast, gives effect to both: it ensures that state positive rules or regulations are preempted, while saving common law liability claims. There is no indication in the text or legislative history of the savings clause that Congress intended to preserve only certain common law claims, as the court of appeals held. See *id.* at A21-A23. And it would be illogical to suppose that, while Congress was explicitly preserving common law claims based on a failure of persons to comply with federal standards, it intended *not* to save such claims when no standard at all was in effect.

B. The Coast Guard's Decision Not To Regulate Propeller Guards Does Not Impliedly Preempt State Common Law Tort Claims Alleging That The Manufacturer Should Have Installed A Propeller Guard

1. This Court has noted that a finding of "implied conflict pre-emption [is appropriate] where it is 'impossible for a private party to comply with both state and federal requirements,' * * * or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Freightliner*, 514 U.S. at 287 (quoting *English*, 496 U.S. at 79, and *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). The Coast Guard's conclusion in 1990 that the available data did not justify the issuance of regulations concerning propeller guards is not a basis for implied conflict preemption of petitioners' common law tort claims.[17]

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[17] Respondent overstates what the Coast Guard decided with respect to propeller guards. The Coast Guard has never formally determined that "a requirement [of propeller guards] would be contrary to the interests of boat safety." Br. in Opp. I (statement of question presented); see also *id.* at 15 ("The Coast Guard determined * * * that propeller guards should not be required because it would make

It would not be impossible for respondent to comply with both state and federal law: there is simply no federal standard with which a private party must comply. Nothing in the FBSA or in the Coast Guard's regulations currently regulates the use of propeller guards. Because the Coast Guard has imposed no standard either mandating or prohibiting propeller guards, motorboat manufacturers are free to install propeller guards or to pay any common law judgments resting on the premise that it was negligent for the manufacturer not to have installed such a device. In this respect, the agency's decision not to promulgate a regulation because the available data did not support one is indistinguishable from *Freightliner*, where a court of appeals had held that the evidence was insufficient to justify the regulation promulgated by the agency. See 514 U.S. at 286-287.[18]

Nor does petitioners' lawsuit frustrate "the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67. Petitioners' common law claims do not hinder in any way the ability of the

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boating *less* safe."). If it had reached that conclusion, the Coast Guard may well have prohibited propeller guards. The Coast Guard stated only that the "[a]vailable propeller guard accident data do not support imposition of a regulation requiring propeller guards." J.A. 163. The Coast Guard's acceptance of the Advisory Council's recommendation does not necessarily constitute an endorsement of all of the information gathered by the Propeller Guard Subcommittee. The subsequent requests by the Coast Guard for public comment on various proposals regarding propeller guards and alternative means of reducing the number of propeller strike deaths and injuries are fully consistent with its conclusion in 1990 that the data at that time did not warrant imposition of a mandatory requirement for propeller guards on all propeller-driven motorboats. See pages 7-8, *supra*.

[18] In *Freightliner*, we filed a brief as *amicus curiae* arguing that a state common law tort action was neither expressly nor impliedly preempted in similar circumstances. See U.S. Br. (No. 94-286).

Coast Guard to promulgate federal regulations regarding propeller guards, should the appropriate justifications for such action be present. See *Freightliner*, 514 U.S. at 289. Under our reading of the savings clause, a common law claim would be permitted even if a regulation were in existence unless that claim propounded a standard of conduct directly contrary to the federal rule. See *CSX Transp.*, 507 U.S. at 676.

2. In holding that petitioners' claims were impliedly preempted (Pet. App. A15-A25), the court below erred. The court misread the FBSA to give the Coast Guard "exclusive authority to issue safety standards." *Id.* at A18; see also *id.* at A20. As we have explained, the congressional intent to achieve uniformity was not so absolute as to leave no room for common law actions. From that erroneous premise, the court then selectively distilled language from this Court's opinions for the proposition that, when an agency has primacy in a particular regulated field, "a federal decision to forgo regulation in a given area may imply an authoritative federal determination that the area is best left *un*regulated, and in that event would have as much preemptive force as a decision *to* regulate." *Id.* at A16 (quoting *Arkansas Elec. Coop. Corp.* v. *Arkansas Pub. Serv. Comm'n*, 461 U.S. 375, 384 (1983)). This Court, however, has not often found those circumstances to exist. In *Arkansas Electric Cooperative* itself, for example, this Court ultimately held that "nothing in the language, history, or policy of the Federal Power Act suggests such a conclusion" that a decision not to issue federal regulations should preempt state regulation. 461 U.S. at 384. And although the court below acknowledged (Pet. App. A16) that "a decision not to regulate does not always have preemptive effect, *see Puerto Rico Dep't of Consumer Affairs* v. *Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988),"

it overlooked a crucial point made by this Court in that case:

> *Transcontinental* [*Gas Pipe Line Corp.* v. *State Oil and Gas Bd. of Miss.*, 474 U.S. 409 (1986)] was not meant to announce a new rule of burden-shifting whenever the Federal Government terminates or reduces its regulation of a field of commerce, replacing the normal need for finding a federal intent to pre-empt with a need to find a federal intent to retransfer authority to the States. To the contrary, a "clear and manifest purpose" of pre-emption is always required.

485 U.S. at 503. Thus, *Arkansas Electric Cooperative*, *Puerto Rico Department of Consumer Affairs*, *Freightliner*, and *Medtronic* all support our view that, as in this case, the absence of a federal regulation does not create a preemptive effect on state common law claims when the federal scheme is not intended to occupy the complete field of motorboat safety.

A different result is not suggested by this Court's decision in *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978).[19]

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[19] The cases on which this Court relied in *Ray* were in areas of well-established federal law concern. See, *e.g.*, *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989) (state intellectual-property action held preempted notwithstanding the absence of an explicit federal regulation in the field because the Court's "past decisions have made clear that state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws"); *Bethlehem Steel Co.* v. *New York State Labor Relations Bd.*, 330 U.S. 767, 774-775 (1947) (failure of National Labor Relations Board to entertain certain actions was actually a determination by the Board "and an exercise of its discretion to determine that [foremen's bargaining units] were not appropriate for bargaining purposes"); *Hines*, 312 U.S. at 66-67 (holding preempted state laws that imposed obligations on aliens because the federal government had enacted a "complete scheme of regulation" and "states cannot, inconsistently with the purpose of Congress, conflict or inter-

That case also involved the Coast Guard, but it concerned a statutory scheme that is quite distinctive from the one at issue here. As the Court explained in *Ray*, the Ports and Waterways Safety Act of 1972 (PWSA) *required* the Secretary to issue "such rules and regulations as may be necessary with respect to the design, construction, and operation of the covered vessels." *Id.* at 161. By contrast, the FBSA takes a different approach: it does not require the Secretary to issue regulations, but rather merely permits him to. Moreover, the FBSA does not address design features of covered vessels in the comprehensive manner addressed in the PWSA. Compare 46 U.S.C. 4302(a) (Secretary "may prescribe regulations establishing minimum safety standards" and "requiring the installation, carrying, or use of associated equipment * * * on recreational vessels subject to this chapter") with 46 U.S.C. 3703(a) ("The Secretary shall prescribe regulations for the design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of vessels to which this chapter applies.") (recodification of 46 U.S.C. 391a(3) (1976), which the Court construed in *Ray*). In addition, the rule at issue in *Ray* was a state prescriptive rule rather than a common law cause of action. That distinction is equally important here, because the FBSA contains a savings clause, but the PWSA, at issue in *Ray*, did not. Pub. L. No. 92-340, 86 Stat. 424.

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fere with, curtail or complement, the federal law, or enforce additional or auxiliary regulations"); *Napier* v. *Atlantic Coast Line R.R.*, 272 U.S. 605, 613 (1926) (holding state positive law preempted because it purported to impose rule in regulatory field already occupied by federal statute, even though the agency "has not seen fit to exercise its authority to the full extent conferred").

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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(2)

No. 99-337

In The
Supreme Court of the United States

JANIS SOWERBY, ET AL.
Petitioners,

v.

PREVO'S FAMILY MARKET, INC., ET AL.
Respondents.

Petition For A Writ Of Certiorari To The Michigan Supreme Court

RESPONDENT SPARTAN STORES, INC.'S BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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September, 1999

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QUESTION PRESENTED FOR REVIEW

Are the plaintiffs' state law claims preempted by the Federal Meat Inspection Act, which expressly prohibits states from imposing requirements that are in addition to or different than the federal act?

PARTIES TO THE PROCEEDINGS

Petitioners

JANIS SOWERBY, as Personal Representative of the Estate of Scott Michael Hinkley, Deceased, And KAREN BOULAHANIS, GEORGE BOULAHANIS, Individually and as next friend of Bridgit Boulahanis, a minor, Karen Boulahanis, a minor and Brian Boulahanis, a minor.

Respondents

PREVO'S FAMILY MARKET, INC., a Michigan corporation, I.B.P., INC., a foreign corporation

and SPARTAN STORES, INC., a Michigan corporation.

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OPINIONS BELOW

The opinion of the Michigan Supreme Court denying leave to appeal is reported at 591 N.W.2d 38 (1999) and is attached as Appendix F to Petitioners' Writ of Certiorari. The opinion Court of Appeals of the Michigan Court of appeals, which affirmed the trial court's dismissal of Petitioners' claims is reported at 230 Mich. App. 131; 582 N.W.2d 509 (1998) and is attached as Appendix A to Petitioners' Writ of Certiorari. The opinion of the Mason County Circuit Court granting Respondents' Motions for summary Disposition is unreported. The circuit court's opinion is attached as Appendix B to Petitioners' Writ of Certiorari

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JURISDICTION

Respondent agrees with the Petitioners' statement of jurisdiction. The Michigan Supreme Court denied Petitioners' Application for Leave to Appeal on May 30, 1999. The

Petition for Writ of Certiorari was filed within ninety days of the issuance of that order. The jurisdiction in the United State Supreme Court is invoked pursuant to 28 U.S.C. § 1257(a).

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CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Respondent agrees with the Petitioners' statement of Constitutional and statutory provisions involved in this matter.

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RESPONDENT'S STATEMENT OF THE CASE

These consolidated cases present tort claims for damages allegedly incurred as a result of consumption of ground beef containing the E. Coli bacteria. In both cases, Petitioners contended that the ground beef at issue was processed by Respondent I.B.P., Inc., sold at wholesale by Respondent Spartan Stores, Inc., and retailed by Respondent

Prevo's Family Market. Petitioners in both cases claimed to purchase the ground beef in mid-July of 1993.

A. Procedural History

Petitioners' cases proceeded in the Circuit Court for the County of Mason, before the Honorable Richard Cooper. Judge Cooper handled both cases on a consolidated basis in view of their common legal and factual issues.

All Respondents moved for summary disposition, arguing that the Federal Meat Inspection Act, 21 USC § 601 et seq, preempted any state law tort remedy. After a hearing on April 22, 1996, the circuit court judge issued an opinion and order on June 25, 1996, granting Respondents' motions. On July 8, 1996, petitioners moved for rehearing, and the circuit court denied that motion by an order entered August 12, 1996. Petitioners appealed to the Court of Appeals by right.

All parties submitted briefs on the federal preemption

issue to the Court of Appeals, and oral argument was heard on January 13, 1998. On June 2, 1998 the Court of Appeals issued a decision for publication which affirmed the ruling of the Circuit Court. From this decision, the Petitioners have filed a Writ of Certiorari.

B. Factual History

These are two product liability cases in which members of two families claim that they ate ground beef which contained a bacteria known as Escherichia Coli 0157:H7 (E. Coli). Apparently in July of 1993 family members from each of the Petitioners' families bought ground meat at Respondent Prevo's Family Market. Allegedly, this meat contained the E. Coli bacteria. Petitioners allege that Kara and Brian Boulahanis suffered from hemolytic uremic syndrome (HUS), and Bridgit Boulahanis suffered pre-HUS as a result of eating this ground beef. Their mother, Karen Boulahanis also allegedly suffered injuries as a result of

eating this ground beef. Plaintiff Janis Sowerby, on behalf of her deceased son's estate, filed a similar suit claiming that her son, Scott Hinkley died as a result of eating ground beef containing the E. Coli bacteria.

Petitioners filed suit against Respondent Prevo's Family Market, Respondent Spartan Stores, and Respondent I.B.P., Inc. The crux of Petitioners' claim is that the meat processed by Respondent I.B.P., Inc., distributed by Respondent Spartan Stores, and sold by Respondent Prevo's Family Market was "adulterated" as defined by the M.C.L. 289.586; M.S.A. 12.964(6) because it allegedly contained the E. Coli bacteria. Petitioners filed suit claiming that the Respondents knew or should have known that the meat contained the E. Coli bacteria, and that the Respondents should have taken measures to prevent its sale or to warn consumers of the possible dangers posed by the meat. The specific claim made by Petitioners was that each Respondent

breached its implied warranty of merchantability and was negligent when it allowed meat containing the E. Coli bacteria to be sold to the Petitioners.

The defense to these claims is very simple. The Federal Meat Inspection Act (FMIA) expressly preempts state law requirements in addition to those made by the FMIA. At the time the meat was purchased, **the E. Coli bacteria was not considered an "adulterant" under the FMIA**. Both the Circuit Court and Court of Appeals have determined that Respondents had no duty to test for or warn the Petitioners of the possibility of E. Coli contamination because such actions were not required by the FMIA. As a result, Petitioners have no cause of action against Respondents.

ARGUMENT I

Neither the Circuit Court Nor the Court of Appeals Erred in Determining That the Federal Meat Inspection Act Preempted

Any State Law Remedy.

A. The Federal Meat Inspection Act Expressly Preempts Any State Law Tort Remedies Which the Petitioners Seek.

The sole issue in Petitioners' Writ of Certiorari is whether the Federal Meat Inspection Act (FMIA) preempts Michigan tort law remedies. The Michigan Court of Appeals, in Kircos v Holiday Food Center, Inc, 191 Mich. App. 82; 477 N.W.2d 130 (1991), explained the three basic mechanisms by which federal law preempts state law.

Preemption can occur if the federal statute expressly preempts state law.

> Congress may, as here, explicitly define the extent to which it intends to preempt state law. The FMIA contains a specific provision expressing Congress' intent that the statute

> and its regulations, in specified areas, have preemptive force over state law.

Id. at 85-86.

Preemption may also occur when the state law conflicts with the federal law. This form of preemption is often called "implied conflict preemption."

> When state law "actually conflicts" with federal law, preemption is also compelled. Such conflict exists when it is impossible to comply with both state and federal law, or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress.

Id. at 86 (citations omitted).

Finally, preemption may also occur when state law conflicts with federal regulations.

> Moreover, preemption is compelled not only

> when the conflict involves a federal statute, but also when it involves valid federal regulations. Provided that they are reasonable exercises of an agency's duly-authorized discretion and not in conflict with congressional intent, federal regulations have no less preemptive effect than federal statutes.

Id. at 86-87.

> The pertinent part of the FMIA reads:
>
> Requirements within the scope of this chapter with respect to . . . any establishment at which inspection is provided . . . which are **in addition to or different than** those made under this chapter may not be imposed by any State. . . . Marking, labeling, packaging, or ingredient requirements **in addition to, or different than** those made under this chapter

> may not be imposed by any State . . . but any State . . . may, **consistent with the requirements under this chapter**, exercise **concurrent jurisdiction** . . . for the purpose of preventing the distribution for human food purposes of any such articles which are **adulterated** . . . and are outside of such an establishment. . . . [Emphasis added].

21 U.S.C. § 678.

In Kircos, the Michigan Court of Appeals ruled that this section of the FMIA "contains a specific provision expressing Congress' intent that the statute and its regulations, in specified areas, have preemptive force over state law." Kircos, 191 Mich. App. at 86. It is clear from the Kircos case that the FMIA and the regulations necessary to carry-out the FMIA shall have preemptive effect over all state laws. The FMIA clearly forbids the states from imposing

inspecting, marking, labeling, or packaging requirements which are "in addition to or different than" those contained in the FMIA.

Furthermore, it is clear that in 1993, when the Petitioners purchased the meat which allegedly contained the E. Coli bacteria, the USDA did not consider the E. Coli bacteria to be an adulterant under the FMIA. The case of Texas Food Industry Ass'n v Espy, 870 F.Supp. 143 (W.D. Tex., 1994) makes this point perfectly clear. In that case, the plaintiffs challenged the USDA's decision to declare the E. Coli bacteria as an adulterant. This declaration meant that the new testing procedures must be implemented by the meat processing industry. The plaintiffs filed suit on the basis that the decision did not conform with the agency's notice requirements. Ultimately, the District Court determined that the notice provisions were not required and that the agency's decision to declare the bacteria as an adulterant under the

FMIA was valid. Id. at 149.

The District Court in Espy made some findings of facts which help define the issues in this case. First, the Court stated that "**[p]rior to this announcement, the USDA had treated pathogen-contaminated meat as unadulterated under FMIA**." Id. at 145 (footnote omitted). The Court also noted in a footnote that testing for the E. Coli bacteria had occurred for several years, and only now had the USDA determined that the bacteria would be considered an adulterant under the FMIA. Id. at 146 fn 6. From these findings it is clear that the USDA chose not to define meat containing the E. Coli bacteria as adulterated prior to 1994.

The Circuit Court granted the Respondents' motions on the basis that FMIA preempted state law tort claims in this area. In support of this position, the Court relied heavily on Kircos, supra. The facts in Kircos are similar to the case at

hand. The plaintiff brought a breach of warranty and negligence action against the defendant because the defendant allegedly sold the plaintiff some pork which contained trichinae from which the plaintiff contracted trichinosis. Kircos, 191 Mich. App. at 84. As previously mentioned, the Court discussed the types of Federal preemption, and determined that the plaintiff's claims were expressly preempted by the FMIA. The FMIA specifically stated that meat containing trichinae was not adulterated. However, under Michigan law, any meat which contained trichinae would be considered adulterated. The Court concluded:

> "Because the requirements of the Michigan statute are "different than" those under the federal scheme, preemption is compelled. Although Michigan has concurrent jurisdiction for the purposes of preventing the distribution of "adulterated" food,

> trichinae-infected pork is not "adulterated" under the federal act. 21 U.S.C. Sec. 678. Accordingly, we find that M.C.L. Sec. 289.716(a)(5); M.S.A. Sec. 12.933(16)(a)(5) cannot be enforced against either defendant. Because the federal statutory scheme provides that there is no duty to inspect or treat fresh pork for trichinae, plaintiff's warranty claims, which are based on assertions of unreasonable risk, must fail as well."

Kircos, 191 Mich. App. at 87.

In the instant case, the Circuit Court determined that the Kircos case was controlling and applied the rule to the case at bar:

> "Further, this Court is bound by the Kircos ruling that there can be no recovery under state tort law. Because federal law and

> regulation had not in 1993 determined Escherichia Coli to be an adulterant, food retailers and meat packers were not required to test for to treat meat in 1993 for Escherichia Coli contamination. . . . [A]s observed above, the Kircos, case specifically states that this subject area is preempted by federal law and regulation and that a tort claim cannot be utilized to seek recovery."

Appendix B to Petitioner's Writ of Certiorari.

The only difference between the case at hand and Kircos is that in Kircos the USDA made it known that meat containing trichinae was not adulterated. The USDA did not determine that the E. Coli bacteria was an adulterant until 1994. By implication any meat containing the E. Coli bacteria before 1994 was not "adulterated" as defined by the FMIA. Therefore, the meat wholesalers, processors, and retailers

were not obligated to inspect for nor warn the public about E. Coli contamination. Under the ruling in Kircos, in 1993, the state of Michigan could not require, as the Petitioners suggest, that the Respondents test for the E. Coli bacteria nor could the state of Michigan require warning labels. **Logically, these requirements would have been in addition to and/or different than the inspection and label requirements required under the FMIA**. For these reasons the Circuit Court correctly determined that the Petitioners claims are preempted by the FMIA.

The Court of Appeals relied heavily Ryan v Brunswick Corp., 454 Mich. 20; 557 N.W.2d 541 (1997) in order to come to the same conclusion. The Court of Appeals determined that the language in the FMIA "includes an express federal preemption provision." (Exhibit 2, p. 3) The Court went on to conclude:

Based on this language, it is clear that

Congress expressly preempted states from placing any additional or different requirements on meat producers other than those of the federal government. Under Ryan and Martinez, supra, any state tort action based on a theory that adulterated meat was distributed must therefore be based on the standards that are identical to federal standards.

Plaintiffs contend that their tort claims are not preempted by federal law because neither Congress nor the USDA adopted regulations concerning the presence of E. Coli bacteria in meat products until 1994, the year after plaintiffs purchased the tainted meat in this case.

*****

In Ryan, supra, p 35, the Supreme Court made it clear that when a federal agency "has deliberately concluded that regulation is not appropriate in a given area, federal inaction will preempt state law not identical to it." That principle applies here. As previously noted, until 1994, the USDA did not consider E. Coli to be an "adulterant." Therefore, the Department did not consider it necessary to inspect for E. Coli and allowed the distribution of E. Coli-contaminated meat. . . . **This intentional decision, not to regulate the presence of E. Coli bacteria in the meat purchased by plaintiffs in 1993 would run contrary to the USDA's then-existing determination that inspection for E. Coli bacteria was not required.**

(Exhibit 2, p 4) (emphasis added)

The Petitioners entire argument is based on the fact that up until 1994, the USDA had not "declared" the E. Coli bacteria to be an adulterant. The Petitioners claim that the USDA's "silence" implies that the USDA did not "make" any regulations regarding E. Coli as an adulterant, and therefore, any state law defining E. Coli as an adulterant would not run contrary to any USDA regulations. This argument is contradictory to this Court's ruling in Ryan. This Court, in Ryan, determined that "[a] decision not to regulate does not automatically invoke preemption, but may carry the force of positive enactment." Ryan, 454 Mich at 35 (footnote omitted) This Court went on to conclude:

> This is not to say that inaction indicated preemption, but rather that "'[w]here a comprehensive federal scheme intentionally leaves a portion of the regulated field without

> controls, *then* the preemptive inference can be drawn - - from federal inaction alone, but from inaction joined with action."

Id. at 35-36 (citations omitted).

Despite Petitioners' arguments to the contrary, this Court's holding in Ryan is directly applicable to the case at hand. The USDA's decision not to include the E. Coli bacteria as an adulterant was clearly an intentional, reasoned determination. The Court of Appeals determined that "[j]ustification was that the painstaking microscopic inspection of meat for pathogens such as E. Coli and salmonella was not feasible and not warranted when any bacteria would be destroyed by the consumer upon proper preparation and cooking of the meat." (Exhibit 2, p 4) The Court of Appeals was convinced that the inaction by the USDA was an intentional decision not to make E. Coli an "adulterant," and therefore, any state law contrary to this

determination would be preempted. Therefore, the Court of Appeals did not err when it relied on the Ryan decision.

B. The Cases Relied on by the Petitioners are Irrelevant to this Case

The Plaintiff relies heavily on the United States Supreme Court cases of Medtronic, Inc. v Lohr, 518 US 470 (1996) and Freightliner Corp. v Myrick, 514 US 280 (1995). However, neither of these case is on point with the case at hand.

In a nut shell, Medtronic involved a claim for personal injuries allegedly caused by a defective pacemaker lead. The suit was filed in the Florida state court and was later removed to the Federal District Court. The defendant claimed that the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 300 et seq, preempted the plaintiff's state law claim. The Court disagreed and found that the plaintiff's claims were not preempted. However, Court's reasons for not preempting the

plaintiff's claims are not applicable to this case.

First, the Supreme Court's decision was based on the fact that the Food and Drug Administration (FDA) has a broad power when determining when the FDCA will preempt state law. The Court noted that the FDA regulations specifically state that preemption does not occur unless the FDA enacted a regulation on that very same subject as the state law or unless there is an unavoidable conflict between the federal law and the state law. Medtronic, Inc.

Already, Medtronic is different than the case at hand in that the FMIA and its regulations, do not require the USDA to expressly rule on the very issue on which the state has ruled. As previously discussed, under the FMIA, the absence of a regulation can be interpreted as regulation on an issue. Therefore, Petitioners reliance in a federal statute which by its own regulations is to be interpreted more strictly is inapplicable to the case at hand.

Furthermore, the Court in Medtronic, Inc. determined that the plaintiff was allowed to bring a state law claim which the plaintiff would have been able to bring under the violation of the federal statute. In the case at hand, Petitioners do not have a federal cause of action. The determination that the E. Coli bacteria was an "adulterant" was not made until a year after the Plaintiff purchased their meat. Therefore, at the time the injury occurred, Petitioners did not have a federal cause of action. Petitioners have filed a state law claim for an injury which has no federal law remedy. These facts are significantly different than the facts in the Medtronic, Inc. case.

The Petitioners also rely on the United States Supreme Court decision in Freightliner Corp v Myrick, 514 US 280 (1995). In that case, the plaintiffs filed suit alleging that the absence of antilock braking systems (ABS) on tractor-trailers manufactures by the defendant constituted a design defect. The defendants argued that such a claim was preempted by

the National Traffic and Motor Vehicle Safety Act of 1966 (the Safety Act), 15 USC §§ 1381 et seq.

In that case this Court determined that the Safety Act and its regulations did not preempt the state law cause of action. The Safety Act specifically limits its preemption to situations where the federal regulations expressly address an issue. This is similar to the Medtronic, Inc. holding. The Court concluded that at the time of the accident, the regulation pertaining ABSs and stopping distances was effectively suspended by a previous Court decision. Therefore, the Safety Act did not expressly address the issue of stopping distances, and therefore, the state law claim was not preempted.

The defendants argued that the Safety Acts silence on the issue can constitute actual regulation. However, the Court stated that there was no evidence that "Congress intended to centralize all authority over the regulated area in one decision

maker: the Federal Government." Id. at 286. However, as previously discussed, the FMIA specifically states that a state can not make any requirements "in addition to or different than" the requirements set forth under the FMIA. Clearly, the claim brought by the Plaintiff seeks to impose requirements in addition to those already placed on the Respondents. Therefore, the Freightliner case has no bearing on this case.

II. The Petitioners' Unsubstantiated Exaggerations and Scare Tactics Do Not State a Valid Reason Why this Court Should Grant Leave for Appeal.

Petitioners, in their first argument, claim that the Court of Appeals decision will have the unintended effect of jeopardizing the health and safety of Michigan Consumers. This argument is clearly made for the sole purpose of "scaring" this Court into granting the Writ of Certiorari. The Petitioners apparently believe that the Michigan people will

not be able to hold meat processors, distributors, and retailers liable for state law claims for new pathogens which may be harmful.

What the Petitioners fail to realize is that they are barking up the wrong tree. The FMIA specifically states that it preempts the state laws in this area. The Court of Appeals merely followed this federal law. The states do not have the power to make requirements in addition to those made by the FMIA or its regulations.

The Petitioners claim that "[t]hese Petitioners are the **only** victims of E. Coli 0157:H7 poisoning in the United States to be denied any tort remedy." (Petitioners Application for Leave to Appeal, p 10) However, **Petitioners have failed to cite one case in which a victim injured prior to 1994 by the E. Coli bacteria was allowed to recover from the meat distributor.** Basically, the Petitioners have failed to cite any cases in which the preemptive effect of the FMIA was not

enforced.

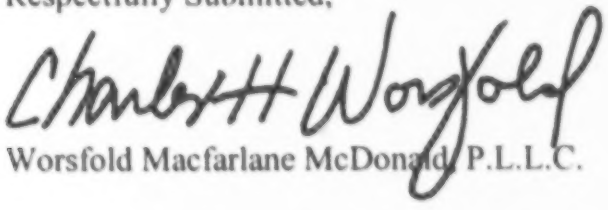
Petitioners exaggerate their claim by comparing this case to the "Jack -in-the-Box" cases which occurred in the early 1990s. However, the Circuit Court in this case already distinguished this case from those cases. The Circuit determined that in the Jack-in-Box cases, the restaurants were being held accountable for failing to properly cook the meat, not for the bacteria in the meat.

The Petitioners have failed to provide any valid reasons why this case should be heard by the United States Supreme Court. The only issue in this case is whether the FMIA has preemptive effect over state law tort claims when it comes to the E. Coli bacteria. Petitioners have failed to provide any cases which show that the FMIA does not have preemptive effect. Furthermore, this Court should not be swayed by the Jack-in-the-Box cases and scare tactics raised by the Petitioners because they have no relevance to this case.

CONCLUSION

For the foregoing reasons, Respondent Spartan Stores, Inc. respectfully requests that this Court deny Petitioners' Writ of Certiorari and/or affirm the Michigan Court of Appeals' ruling.

Respectfully Submitted,



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Supreme Court, U.S.
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(3)

No. 99-337

In The

Supreme Court of the United States

JANIS SOWERBY, as Personal Representative of the Estate of SCOTT MICHAEL HINKLEY, deceased, KAREN BOULAHANIS, GEORGE BOULAHANIS, individually and as next friend of BRIDGIT BOULAHANIS, a minor, KARA BOULAHANIS, a minor and BRIAN BOULAHANIS, a minor,

Petitioners,

v.

PREVO'S FAMILY MARKET, INC., a Michigan Corporation, IBP, INC., a Foreign Corporation and SPARTAN STORES, INC., a Michigan Corporation,

Respondents.

On Petition For Writ Of Certiorari To The Michigan Court Of Appeals

RESPONDENT IBP, INC.'S BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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1999

QUESTION PRESENTED

Whether this Court should deny review, as did the Michigan Supreme Court, of the decision of the Michigan Court of Appeals affirming the trial court's summary dismissal of Petitioners' state law tort claims on the ground that those claims are preempted by the Federal Meat Inspection Act, which expressly prohibits states from imposing requirements that are "in addition to, or different than" those contained in the Act.

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OPINIONS BELOW

The Order of the Michigan Supreme Court, denying Petitioners' Request for Leave to Appeal, is reported at 591 N.W.2d 38 (Mich. 1999) (Petitioners' Appendix F). The Opinion of the Michigan Court of Appeals is reported at 583 N.W.2d 509 (Mich. Ct. App. 1998) (Petitioners' Appendix A). The Opinions of the Circuit Court for the County of Mason, State of Michigan were not reported (Petitioners' Appendix B).

STATEMENT OF JURISDICTION

Respondent IBP does not contest Petitioners invoking jurisdiction pursuant to 28 U.S.C. § 1257(a).

CONSTITUTIONAL PROVISION INVOLVED

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. CONST. Art. VI, cl. 2.

RESPONDENT IBP'S STATEMENT OF THE CASE

In this fact-specific case, Petitioners allege that in 1993 they suffered injuries caused by ingesting Escherichia Coli 0157:H7 bacteria ("E. Coli"). They claim the source of the E. Coli was ground beef, which was sold by Prevo's Family Market, distributed by Spartan Stores, Inc., and processed by IBP, inc. ("IBP").[1]

In their depositions, Petitioners admitted that there were numerous other sources of E. Coli to which they were exposed (i.e., milk, lake water, fruits and vegetables). Respondents contend that Petitioners cannot establish that their injuries were caused by eating ground beef; however, for purposes of their motions for summary disposition and for these proceedings, Respondents accept as true the assumption that the source of E. Coli was ground beef purchased at Prevo's Family Market.

The processing of meat at IBP is regulated by the U.S. Department of Agriculture ("USDA") acting in conformity with the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. § 601, *et seq*. Congress established this regulatory scheme in order to develop and administer uniform, national meat inspection programs. 21 U.S.C. § 661. USDA inspectors conduct an "examination and inspection" of all meat and "mark, strap, tag or label as inspected and passed all such products found to be not adulterated . . . " 21 U.S.C. § 606.

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[1] As required by Supreme Court Rule 29.6, IBP states that it has no parent company and that any subsidiaries of IBP are wholly owned by IBP, inc.

In 1993, there were twenty-one USDA inspectors who worked full time at IBP's Lexington, Nebraska facility, where the meat at issue was produced. These federal officials examined and inspected every carcass and stamped it "inspected and passed" before it was placed into commerce.

Respondents moved for summary disposition based upon the express preemption provision of the FMIA which prohibits states from imposing any requirements in addition to or different from those required by the federal Act. 21 U.S.C. § 678. The trial court granted that motion, reasoning that the FMIA clearly preempts any requirement to provide any labeling, testing or inspection in addition to or different than that required by the federal statutory scheme. Moreover, because federal law and regulation had not determined E. Coli to be an adulterant in 1993, meat packers and retailers were not required to test or inspect meat for E. Coli contamination at that time. Therefore, Michigan's concurrent jurisdiction over the distribution of adulterated products was inapplicable. Consequently, the trial court correctly held that Petitioners' state tort claims were preempted by federal law and regulation.

The Michigan Court of Appeals affirmed the trial court, and the Michigan Supreme Court denied Petitioners' application for discretionary review of that decision.

RESPONDENT IBP'S ARGUMENT

Respondent IBP contends that this case presents none of the compelling reasons set forth in Supreme Court Rule 10 for granting certiorari in this case.

First, the decision in this case has very narrow application. This case involves two families who claim that in 1993 they ate ground beef that contained E. Coli bacteria. At that time, the United States Department of Agriculture had determined that E. Coli was not an adulterant in meat. That regulation changed in September 1994. There are no other lawsuits in Michigan involving pre-1994 E. Coli-contaminated meat. Thus, the issue presented applies only to the Petitioners in this lawsuit, not, as Petitioners argue, to all Michigan consumers.

Second, the decision in this case does not conflict with the decision of any other court. Petitioners imply that every state except Michigan has ruled that claims such as Petitioners' are not preempted by federal law (Petition, pp. 8-9). This implication is absolutely false. Petitioners have cited no case law to support their position, because there is none. Contrary to Petitioners' misleading argument, Respondent IBP asserts that the decision below is consistent with both federal and state law, which support the statutory scheme established by Congress in the Federal Meat Inspection Act for regulating the meat industry.

Third, the decisions below comport with the compelling public policy that undergirds the preemption doctrine – the maintenance of a uniform national system of regulating interstate commerce, in this case, the meat

industry. The Federal Meat Inspection Act serves to protect public health while also preventing and eliminating the burden on commerce that would result from divergent regulation by the various states. The decision of the Michigan Court of Appeals foreclosed the dangerous precedent urged by Petitioners that would permit a state to impose tort liability contrary to a federal statute. Applied to the circumstances presented here, such a precedent would disrupt commerce by exposing a meat producer to differing duties and requirements among the 50 states. Further, the position pressed by Petitioners would permit states to impose liability for conduct that occurs before the applicable regulatory body (the USDA) takes action; i.e., a state court could impose liability on a meat producer for injuries due to a pathogen that the USDA has declared is not an adulterant in meat. Such a consequence is inimicable to the express preemption of the Federal Meat Inspection Act, which forbids states from imposing any requirements that are in addition to or different than those in the Act and which declares that only the USDA has the authority to determine what is an adulterant in meat.

The Federal Meat Inspection Act Expressly Preempts State Law

The doctrine of federal preemption has its origin in the Supremacy Clause of the Constitution which declares that the laws of the United States "shall be the supreme Law of the Land . . . " U.S. CONST. Art. VI, cl. 2. Thus, where federal preemption applies, state courts are deprived of subject matter jurisdiction.

A federal statute will not be presumed to "supersede the exercise of power by the State unless there is a clear manifestation of intention to do so." *New York Dep't of Social Serv. v. Dublino*, 413 U.S. 405, 413 (1973). The United States Supreme Court, the Sixth Circuit Court of Appeals, and the Michigan Court of Appeals have all held that by enacting 21 U.S.C. § 678, Congress clearly intended that the FMIA preempt state law in the field. *Jones v. Rath Packing Co.*, 430 U.S. 519, 530-531 (1977); *Armour & Co. v. Ball*, 468 F.2d 76, 83 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973), quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963) ("In 21 U.S.C. § 678 'Congress has unmistakably so ordained' federal regulation of a field of commerce"); *Kircos v. Holiday Food Ctr.*, 477 N.W.2d 130, 131 (Mich. Ct. App. 1991) ("The FMIA contains a specific provision [21 U.S.C. § 678] expressing Congress' intent that the statute and its regulations, in specified areas, have preemptive force over state law.").

The extent to which Congress intended the FMIA to preempt state law claims is evident from the statute's "congressional statement of findings."

> Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. . . . It is hereby found that all articles and animals which are

> regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

21 U.S.C. § 602. In its statement of findings, Congress declared that it has already considered the protection of the consumer from unwholesome, adulterated and misbranded meat and has determined that the public interest would be best served by enforcement of a unified system of regulation pursuant to federal law and federal law alone.

Congress' intent is also clear from the express preemption clause of the statute which states, in pertinent part:

> Requirements within the scope of this chapter with respect to . . . any establishment at which inspection is provided . . . which are **in addition to, or different than** those made under this chapter may not be imposed by any State . . . Marking, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this chapter may not be imposed by any State . . . but any State . . . may, consistent with the requirements under this chapter, exercise concurrent jurisdiction . . . for the purpose of preventing the distribution for human food purposes of any such articles which

> are adulterated . . . and are outside of such an establishment . . .

21 U.S.C. § 678 [emphasis added].

The extent to which Congress intended the FMIA to preempt state law claims is further evident in the extensive regulatory scheme of the statute. Congress authorized the U.S. Secretary of Agriculture to develop and administer meat inspection programs to effectuate the threefold purpose of the Act (to prevent and eliminate burdens on commerce, to regulate the meat industry, and to protect the health of customers). 21 U.S.C. § 661. It is the task of the U.S. Department of Agriculture to make any rules and regulations that are necessary to effectuate these purposes. 21 U.S.C. § 621.

States are prohibited from imposing any "requirements" that are "in addition to, or different than" those promulgated by the U.S. Department of Agriculture. 21 U.S.C. § 678. The federal "requirements" referred to in Section 678 include not only that statutory provision but also USDA regulations and administrative actions such as the on-site USDA meat inspections and approvals conducted at meat processing facilities. To impose additional and different state requirements would contravene the public policy of the preemption doctrine. That public policy, as stated in the Act, "to prevent and eliminate burdens upon such commerce," is intended to protect companies from the imposition of varying requirements in the 50 states so that they are not subjected to differing duties among the many states where they do business. Thus, it was Congress' purpose to promote uniformity

not only in protecting the consumer, but also in protecting those engaged in commerce from potentially conflicting requirements of the various states.

A. Petitioners' Tort Claims Are Preempted Because They Are In Addition To And Different Than The FMIA

Petitioners claim breach of implied warranty and negligence in selling ground beef that allegedly contained E. Coli bacteria and in failing to label ground beef to advise customers that they must thoroughly cook ground beef in order to destroy the E. Coli bacteria. The preemption of Petitioners' negligence and implied warranty claims under 21 U.S.C. § 678 can best be understood by comparing the specific federal "requirements" applicable to meat production with the "state requirements" or duties Petitioners attempt to impose upon meat production.

To enforce the Act's prohibitions and policies, Congress authorized the U.S. Secretary of Agriculture/U.S. Department of Agriculture ("USDA") to develop and administer uniform, national meat inspection programs. 21 U.S.C. § 661. The USDA also has the exclusive authority to effectuate the purpose and enforcement of the Act. 21 U.S.C. § 621; *see* 9 C.F.R. 317 *et seq.* Inspectors, who are appointed by the USDA and act under its authority, conduct an "examination and inspection" of all meat and "mark, strap, tag or label as inspected and passed all such products found to be not adulterated . . . " 21 U.S.C. § 606.

In 1993, 21 USDA inspectors worked full time in IBP's Lexington, Nebraska slaughterhouse facility, where the allegedly contaminated meat was produced. These federal officials examined and inspected every carcass and stamped it "inspected and approved" before it was placed into commerce. As the trial court correctly observed, "By passing inspection, the meat was deemed fit for shipping and distribution." (Petitioners' Appendix B, p. 2).

The only exception to the express preemption provision of the FMIA is that the statute permits states to exercise concurrent jurisdiction as to meat that is adulterated. The term "adulterated" is defined at length in 21 U.S.C. § 601(m). The USDA did not consider meat containing bacteria, such as E. Coli "adulterated" in July of 1993 when Plaintiffs' cause of action arose. It was not until September 29, 1994, more than one year after Petitioners consumed the allegedly contaminated ground beef, that the USDA announced **for the first time** its new policy position that E. Coli bacteria was an adulterant.

Thus, when Petitioners' claim arose in 1993, there was no duty to test for E. Coli. Consequently, the Michigan Court of Appeals correctly found that to hold "defendants liable for failing to detect the presence of E. Coli bacteria in the meat purchased by Petitioners in 1993 would run contrary to the USDA's then-existing determination that inspection for E. Coli bacteria was not required." *Boulahanis v. Prevo's Family Mkt., Inc.*, 538 N.W.2d 509 (Mich. Ct. App. 1998), *appeal denied sub nom. Sowerby v. Prevo's Family Mkt., Inc.*, 591 N.W.2d 38 (Mich. 1999).

B. Petitioners' State Law Claims Are Preempted Because They Do Not Fall Within Michigan's Concurrent Jurisdiction Over Distribution Of Adulterated Meat Products

Petitioners argue that their claims are permissible under Section 678 as a "concurrent" state requirement because they would impose duties "consistent with Federal law." (Petition, pp. 13-14). Section 678 does permit states to exercise concurrent jurisdiction to prevent distribution of adulterated products. But the USDA, and only the USDA, must first determine whether the product is adulterated. Petitioners misconstrue this clause as somehow sanctioning their lawsuit because after their claims arose, the USDA classified meat containing E. Coli as "adulterated."

The USDA's decision to treat meat containing E. Coli as adulterated does not have retroactive effect. 5 U.S.C. § 551(4) (agency rules can only have prospective effect); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 209 (1988) ("administrative rules will not be construed to have retroactive effect unless their language requires this result"); *see also Landgraf v. USI Film Products*, 511 U.S. 244, 268 (1994) ("statutory retroactivity has long been disfavored"). Therefore, in order for a state to exercise concurrent jurisdiction, the state's requirements must be consistent with then existing federal requirements *not* with regulations that are made at a later date.

Petitioners also argue that just because the USDA did not consider meat containing E. Coli as adulterated until 1994, "does not mean that it was not, in fact and in law, adulterated prior to that time." (Petition, p. 15). That,

however, is precisely what it means; that is how federal preemption works. The FMIA expressly provides that the USDA, and the USDA alone, has authority to develop meat inspection programs and to make the rules and regulations necessary to effectuate the enforcement and purposes of the FMIA. 21 U.S.C. § 621, § 661. If E. Coli is to be deemed an adulterant, "it is the United States Secretary of Agriculture who must speak. When he fails to speak or misspeaks his authority, the state cannot substitute its voice." *Rath Packing Co. v. Becker*, 357 F. Supp. 529, 535 (C.D. Cal. 1973), *aff'd in part, rev'd in part*, 530 F.2d 1295 (9th Cir. 1975), *aff'd sub nom. Jones v. Rath Packing Co.*, 430 U.S. 519 (1979). In this case, as in *Rath Packing*, even if "the evidence here shows the United States Department of Agriculture may have abdicated some of its protective duty" by not treating meat containing E. Coli as adulterated until 1994, that "does not justify the application of a *different* . . . requirement by the state. . . . " *Id.*

Petitioners' federal "silence" argument (Petition, pp. 20-22) is likewise unpersuasive. In *Armour & Co. v. Ball*, the Sixth Circuit Court of Appeals rejected the argument that the "silence" of federal regulations allowed state regulation, and the court preempted the state requirement at issue under 21 U.S.C. § 678. The court held that even though federal regulations had made no provision for a particular type of sausage, the state was not permitted to interpose its own regulation. *Armour*, 468 F.2d at 85.

Furthermore, "a federal decision to forego regulation in a given area may imply an authoritative federal determination that the area is best left unregulated, and in that

event would have as much pre-emptive force as a decision to regulate." *Arkansas Elec. Coop. Corp. v. Arkansas Pub. Serv. Comm'n*, 461 U.S. 375, 384 (1983). Consistent with this body of case law, the Michigan Court of Appeals correctly held that the USDA's "intentional decision not to regulate the presence of E. Coli because it was not considered an adulterant carries the force of a positive enactment." *Boulahanis*, 583 N.W.2d at 512, citing *Ryan v. Brunswick Corp.*, 557 N.W.2d 541 (Mich. 1997).

C. The Trial Court Correctly Relied On *Kircos v. Holiday Food Ctr.*

The Michigan Court of Appeals was confronted with the same set of common-law actions, the same federal statute and the same express preemption issue in *Kircos v. Holiday Food Ctr.*, 477 N.W.2d 130 (Mich. Ct. App. 1991), *appeal denied*, 487 N.W.2d 412 (Mich. 1992) as are present in this case. There, plaintiff brought negligence and breach of implied warranty actions, based upon the same Michigan statute upon which Petitioners rely. Plaintiff alleged that defendant sold him pork containing trichinae from which he contracted trichinosis. The court concluded that the plaintiff's claims were expressly preempted by the FMIA pursuant to 21 U.S.C. § 678.

The court held: "Because the requirements of the Michigan statute are 'different than' those under the federal scheme, preemption is compelled. Although Michigan has concurrent jurisdiction for the purposes of preventing the distribution of 'adulterated' food, trichinae-infected pork is not 'adulterated' under the federal act [FMIA]." *Kircos*, 477 N.W.2d at 132. Similarly,

meat containing E. Coli was not "adulterated" under the FMIA in 1993, when Petitioners' cause of action arose; therefore, their claims would impose requirements different than those under the federal scheme and preemption is compelled.

The *Kircos* court also dismissed plaintiff's warranty claims, reasoning: "Because the federal statutory scheme provides that there is no duty to inspect or treat fresh pork for trichinae, plaintiff's warranty claims, which are based on assertions of unreasonable risk, must fail as well." *Id.* Likewise, in the instant case, Petitioners' claim for breach of implied warranty was correctly dismissed because there was no duty to inspect meat for E. Coli under the preemptive FMIA and USDA regulation in 1993.

CONCLUSION

The Michigan Court of Appeals correctly affirmed the summary dismissal of Plaintiffs' claims as preempted by the Federal Meat Inspection Act, 21 U.S.C. § 678. The U.S. Department of Agriculture has the sole authority to determine whether meat is adulterated. Because the USDA had not declared E. Coli an adulterant in 1993, when Plaintiffs' claims arose, there was no duty to inspect or test for E. Coli. The FMIA provides that states may not, via a tort claim, impose a duty to inspect or test for E. Coli, as such a duty would be in addition to or different than the requirements of the Act.

Petitioners have not shown grounds why this Court should grant certiorari. Because of the 1994 change in the

federal regulation, the decision in this case is only applicable to the Petitioners. More fundamentally, the lower courts' decisions were correct in that they are consistent with the compelling public policy of providing uniform federal regulation of the meat industry.

For these reasons, and for those given in Respondents Prevo's and Spartan's briefs in opposition, the Petition should be denied.

Respectfully submitted,

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Supreme Court, U.S.
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No. 99-337

IN THE

Supreme Court of the United States

JANIS SOWERBY, As Personal Representative of the Estate of SCOTT MICHAEL HINKLEY, deceased, KAREN BOULAHANIS, GEORGE BOULAHANIS, individually and as next friend of BRIDGIT BOULAHANIS, a minor, KARA BOULAHANIS, a minor and BRIAN BOULAHANIS, a minor,

Petitioners,

v.

PREVO'S FAMILY MARKET, INC. a Michigan Corporation; I.B.P., INC. a Foreign Corporation and SPARTAN STORES, INC., a Michigan Corporation, Jointly and Severally,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE MICHIGAN COURT OF APPEALS

BRIEF IN OPPOSITION FOR RESPONDENT PREVO'S FAMILY MARKET, INC.

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STATEMENT OF QUESTION INVOLVED

Whether the Federal Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*, preempts the petitioners' state law claims for negligence and breach of warranty and the respondents are, therefore, entitled to a summary disposition dismissing those claims.

STATEMENT PURSUANT TO RULE 29.6

Respondent, Prevo's Family Market, Inc., has no parent corporation and no publicly held company owns 10% or more of its stock.

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STATEMENT OF THE CASE

1. The Boulahanis Case.

The Boulahanis case arises out of injuries to several minor petitioners allegedly caused by their consumption of ground beef infected with the bacteria Escherichia coli 0157:H7 ("E. coli"). That beef was allegedly purchased at respondent Prevo's Family Market, Inc. ("Prevo's").

2. The Sowerby Case.

The Sowerby case arises out of the death of petitioner's son. As in *Boulahanis*, this injury allegedly resulted from the consumption of ground beef infected with E. coli bacteria. Once again that beef was allegedly purchased at Prevo's.

3. The Respondents.

Respondent Prevo's Family Market, Inc., is an individually-owned chain of stores in the northwest region of Michigan that operates a supermarket in Mason County, Michigan. The two remaining respondents are I.B.P., Inc., a slaughterhouse and Spartan Stores, Inc., a distributor of food products.

4. The Petitioners' Claims.

As a consequence of their injuries, the petitioners filed suit against the respondents in the Circuit Court for Mason County Michigan. The petitioners in both cases asserted claims for breach of implied warranty of merchantability and various forms of negligence.

5. Prevo's Motions for Summary Disposition.

In response to the petitioners' complaints in both *Boulahanis* and *Sowerby*, respondent Prevo's filed motions for summary disposition pursuant to Michigan court rule MCR

2.116(C)(10). Those motions were based on the following contentions:

A. The petitioners' claims in both cases were based on allegations that Prevo's had sold ground round steak that was contaminated with E. coli bacteria.

B. The Federal Meat Inspection Act, 21 U.S.C. §§ 601 *et seq.*, as amended by the Wholesome Meat Act, 21 U.S.C. § 601-695, ("FMIA" or "the Act") specifically prohibits Michigan from imposing conflicting standards or requirements on a retail establishment for adulterant determination, inspection, labeling, or warning.

C. E. coli bacteria was not deemed to be an "adulterant" in July 1993 within the meaning of the FMIA.

D. Michigan law is preempted by the FMIA and under the FMIA the petitioners have no valid claim against Prevo's.

6. The Trial Court's Decision.

The trial court heard Prevo's motion for summary disposition on April 22, 1996. After the court heard oral argument and later reviewed supplemental briefs it had requested concerning the so-called "Jack-in-the-Box" cases, the court concluded that Prevo's motion should be granted; and it did so in an order entered on June 25, 1996.

The petitioners subsequently filed a Motion for Rehearing and Reconsideration, claiming that the decision of the United States Supreme Court in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) required a different conclusion on the question of preemption; but the trial court disagreed with that contention and denied the petitioners' motions in an order entered August 12, 1996.

The petitioners then appealed from the orders granting Prevo's a summary disposition and denying their Motion for Rehearing and Reconsideration.

7. The Decision of the Michigan Court of Appeals.

The Michigan Court of Appeals issued its decision in this matter on June 2, 1998 (Petitioners' Appendix A). In that decision the court concluded that the federal government's refusal to declare E. coli an "adulterant" until 1994 had the force of a positive determination that inspection of meat for E. coli was not required. Thus, the Court of Appeals concluded that the petitioners' claims were preempted by federal law and that all of the respondents were entitled to a summary disposition of those claims.

> In *Ryan* [v *Brunswick Corp*, 454 Mich. 20; 557 N.W.2d 541 (1997)] p 35, the Supreme Court made it clear that when a federal agency "has deliberately concluded that regulation is not appropriate in a given area, federal inaction will preempt state law not identical to it." That principle applies here. As previously noted, until 1994, the USDA did not consider E. coli to be an "adulterant." Therefore, the Department did not consider it necessary to inspect for E. coli and allowed the distribution of E. coli contaminated meat. The justification was that the painstaking microscopic inspection of meat for pathogens such as E. coli and salmonella was not feasible and not warranted when any bacteria would eventually be destroyed by the consumer upon proper preparation and cooking of the meat. See *American Public Health Ass'n* v *Butz*, 167 U.S. App. D.C. 93; 511 F.2d 331, 332, 334 (1974). This intentional decision, not to regulate the presence of E. coli because it was not considered an adulterant, carries the force of a positive enactment. *Ryan*,

> *supra*. Holding defendants liable for failing to detect the presence of E. coli bacteria in the meat purchased by petitioners in 1993 would run contrary to the USDA's then-existing determination that inspection for E. coli bacteria was not required. The trial court therefore properly concluded that petitioner's claims were preempted by federal law.

Boulahanis v. Prevo's Family, Market, Inc., 230 Mich. App. 131, 137, 583 N.W. 2d 509 (1998).

8. The Decision of the Michigan Supreme Court.

The petitioners then sought to have the Michigan Supreme Court review the decision rendered by the Court of Appeals, but the Supreme Court denied their request for such review in an order issued on March 30, 1999 (Petitioners' Appendix F).

REASON FOR DENYING THE WRIT

THE FEDERAL MEAT INSPECTION ACT, 21 U.S.C. §§ 601 *et seq.*, PREEMPTS THE PETITIONERS' STATE LAW CLAIMS FOR NEGLIGENCE AND BREACH OF WARRANTY AND THE RESPONDENTS ARE, THEREFORE, ENTITLED TO A SUMMARY DISPOSITION DISMISSING THOSE CLAIMS.

1. The Preemption Doctrine.

There are three circumstances in which federal law preempts state law:

> First, Congress can define explicitly the extent to which its enactments pre-empt state law. * * * Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. * * * Finally, state law is pre-empted to the extent that it actually

> conflicts with federal law. Thus, the Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

English v. General Electric Co., 496 U.S. 72, 78-79 (1990).

2. The Preemption Provision of the FMIA, 21 U.S.C. § 678.

21 U.S.C. § 678 contains the preemption provision of the FMIA. It provides as follows:

> Requirements within the scope of this chapter with respect to premises, facilities and operations of any establishment at which inspection is provided under subchapter I of this chapter, which are *in addition to, or different than* those made under this chapter may not be imposed by any State * * * . Marking, labeling, packaging, or ingredient requirements *in addition to, or different than*, those made under this chapter may not be imposed by any State * * * but any State * * * may, *consistent with the requirements under this chapter*, exercise *concurrent jurisdiction* * * * for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment * * * . This chapter shall not preclude any State * * * from making requirements or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

21 U.S.C. § 678 (emphasis added).

It is clear from this material that the FMIA forbids the states to impose inspecting, marking, labeling, or packaging requirements that are "in addition to or different than" those contained in the Act.

It is also clear that the instant cases involve the first type of preemption described above — preemption resulting from an express Congressional declaration that the FMIA and any regulations based on it shall have preemptive effect.

The petitioners consistently overlook this fact; and, as a consequence of their doing so, virtually all of their arguments fail to discuss the issues actually involved in this appeal. The petitioners' arguments might be suitable in cases involving preemption that results from the mere conflict of state and federal laws, but those arguments say nothing that is relevant to cases in which preemption is expressly mandated by the federal statute itself.

3. The FMIA Has Preemptive Effect in this Case.

A. *The Petitioners' Arguments Rest on an Incorrect Assumption and Are Invalid for that Reason.*

The petitioners' petition is largely devoted to a single argument which they restate a number of times in somewhat different fashion. The argument asserts that the doctrine of preemption does not apply in this case because prior to 1994 the federal government had supposedly failed to make any regulations concerning meat containing E. coli bacteria. The following statements from the petitioners' petition are illustrative of their repeated claims to that effect.

> * * * Thus, where the condition of which the Petitioners complain, and as to which the Petitioners assert common law theories of recovery, is not federally regulated, and is the

> subject to no federal requirements, either directly under the statute or by regulation, state law claims should be allowed.

(Petition, pp. 13-14.)

* * *

> * * * That the Federal government had not yet determined, at the time of Petitioners' consumption of the meat, that the meat was adulterated for having E. coli within it does not mean that it was not, in fact and in law, adulterated prior to that time.

(Petition, p. 15.)

* * *

> * * * There was no Federal regulation or regulatory action by the Federal Meat Inspection Agency prior to 1994. * * *

(Petition, p. 17.)

The arguments the petitioners base on the alleged failure of the federal government to regulate meat containing E. coli bacteria are erroneous for several reasons.

First of all, they are irrelevant to the issues involved in this appeal because the preemption involved in the underlying cases is mandated by 21 U.S.C. § 678. The preemptive effect of the FMIA thus does not depend in any way on the existence of a conflict between state and federal laws; and it is consequently immaterial whether, prior to 1994, the federal government had decided whether meat containing E. coli was adulterated. The FMIA has preemptive effect because it is a federal statute and says that it preempts state law. Nothing more is needed.

The petitioners further err in claiming that prior to 1994 the federal government had not spoken on the issue of E. coli in meat. Thus, the fundamental assumption underlying virtually all of their arguments is simply wrong.

The fact that, prior to 1994, the United States Department of Agriculture ("USDA") declined to classify meat containing E. coli bacteria as "adulterated" was fully equivalent to an affirmative decision that such meat was not "adulterated" and could be sold for human consumption. The petitioners' attempt to transform this obviously deliberate decision by the USDA into a failure to act is nonsense.

After all, 1993 was not that long ago; and the dangers associated with the contamination of food by E. coli were well known at that time. 1994 was not the year when the USDA first become aware of the dangers posed by meat containing E. coli, and it had undoubtedly considered the status of E. coli as an adulterant before that time. As long ago as 1975 the status of salmonella bacteria as an "adulterant" was litigated, and it was decided that the presence of salmonella in meat did not constitute adulteration within the definition established by 21 U.S.C. § 601(m). *American Public Health Ass'n. v. Butz*, 511 F.2d 331, 334 (5th Cir. 1975). The presence of bacteria in meat was clearly an issue that has occupied the USDA for many years, and the petitioners' repeated assertions that the USDA never gave any thought to the status of E. coli as an adulterant and made no decision on that question prior to 1994 is clearly wrong.

Furthermore, the Supreme Court of the United States has expressly recognized that a decision not to regulate is itself regulation whenever the federal government intended to centralize all authority over the regulated area in one decision maker; and that is precisely the situation where the USDA and regulation of standards for meat are concerned. *Ray v. Atlantic Richfield Co.*, 435 U.S. 151 (1978).

Unfortunately for the petitioners' arguments in this case, until 1994 the USDA held the view that meat containing E. coli bacteria was not adulterated; but its doing so is obviously far different from making no decision at all on that question.

The court in *Texas Food Industry Ass'n. v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994) properly interpreted the USDA's decision in 1994 to declare E. coli an adulterant and labeled that decision a change in its prior policy of viewing meat containing E. coli as not adulterated.

> * * * Prior to this announcement, the USDA had treated pathogen-contaminated meat as unadulterated under the FMIA.

870 F. Supp. 143, 145.

* * *

> * * * Finally, the Court finds that the Defendants' changing policy is a rational response to an emerging problem.

870 F. Supp. 143, 148.

The court in *Texas Food* also pointed out that the USDA had been sampling and testing meat for E. coli bacteria for several years before declaring that bacteria an adulterant (870 F. Supp. 143, 146, fn. 6), and obviously the presence of E. coli in meat had been a matter of concern to the USDA for a considerable amount of time before it declared such bacteria an adulterant in 1994.

A decision not to label certain meat as adulterated is a decision even though it results in no action; and when, prior to 1994, the USDA declined to label meat containing E. coli as adulterated it made a decision that such meat was not, in fact,

adulterated. The petitioners' repeated claims to the contrary have no merit and are clearly wrong.

B. *The Michigan Supreme Court Properly Decided Ryan v. Brunswick Corp, 454 Mich. 20, 557 N.W.2d 541 (1997), and the Michigan Court of Appeals Properly Relied on that Decision When It Concluded that Federal Law Preempts the Petitioners' Claims.*

The decision in *Ryan v. Brunswick Corp.*, 454 Mich. 20, 557 N.W.2d 541 (1997) shows quite clearly that federal law preempts the petitioners' claims. *Ryan* properly concluded that a refusal to regulate can itself be considered a form of regulation, especially where no federal standards or requirements are imposed even after a particular problem has been identified and studied. That portion of *Ryan*'s holding is based on solid federal precedent and is consistent with well-established law. 454 Mich. 20, 35-36.

This part of *Ryan*'s holding provides the answer to the petitioners' repeated assertions that no preemption can occur in this case because prior to 1994 the USDA did not consider E. coli bacteria to be an adulterant. The USDA certainly knew that the presence of such bacteria in meat presented a possible problem, and it studied that problem for several years before declaring E. coli an adulterant. *See Texas Food Industry Ass'n. v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994). *See also American Public Health Ass'n. v. Butz*, 511 F.2d 331, 334 (5th Cir. 1975). (Salmonella bacteria was not an adulterant in meat as that term is defined in 21 U.S.C. § 601(m)).

Given this awareness of the possible problem posed by E. coli in meat and the study of that problem prior to 1994, the USDA's decision not to declare E. coli an adulterant was fully equivalent to an express decision that it was not then an adulterant. Thus, even if it were necessary for the federal government to exert its regulatory power in this area for

preemption to occur (a clearly incorrect assumption given the nature of the express preemption provision found in 21 U.S.C. § 678), such regulation did in fact occur; and the decision in *Ryan* strongly supports that conclusion. The petitioners' claims to the contrary are clearly wrong.

Ryan also holds that "state law" includes common law actions for damages. This conclusion is also clearly correct and is, once again, based on established federal precedent. A common law action may be a form of state law or regulation that is preempted by federal law because the possibility of a damage award can compel someone to do something federal law does not require. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236 (1959).

This portion of *Ryan* answers the petitioners' claims that their common law claims somehow fall outside the scope of the preemption doctrine and survive despite it.

The petitioners' analysis of *Ryan* is furthermore dead wrong because it ignores the nature of the preemption provision involved in that case. By doing so it fails to comprehend the question actually presented in that case.

Given the preemption provision and saving clause involved in the Federal Boat Safety Act, the Supreme Court of Michigan in *Ryan* concluded that preemption occurred only when a state law or regulation was not identical to an *existing* federal regulation (454 Mich. 20, 30, fn. 12). Thus, in *Ryan* it was necessary for a federal regulation inconsistent with a state law or regulation to exist before preemption could take place. It was for that reason that the Michigan Supreme Court considered the intention of Congress in deciding not to require guards on boat propellers. In order to answer the preemption question presented in *Ryan* it was necessary to determine whether the refusal of Congress to require such guards was equivalent to an express determination that such guards were not necessary.

This case necessitates no such inquiry. The preemption provision involved in this matter expressly prohibits a state from enacting any requirement "in addition to" those imposed by the FMIA, and thus it is not necessary to find a conflict between a state law or regulation and an existing federal regulation before preemption occurs. The preemption provision in 21 U.S.C. § 678 invalidates any state law or regulation that imposes an additional "marking, labeling, packaging, or ingredient" obligation on any entity subject to the FMIA regardless of whether the federal government has enacted any regulations in that area or not. The petitioners' claim that a *Ryan*-type analysis of Congressional intent is required in this case thus has no merit.

C. *Even If the Federal Government Had Not Established a Policy Concerning Meat Contaminated with E. Coli Prior to 1994, State Regulation of Meat Containing Such Bacteria Would Still Have Been Preempted.*

Any Michigan law concerning meat containing E. coli would have been preempted in 1993 even if the federal government had failed to determine that such meat was not adulterated. The FMIA does not merely prohibit state laws and regulations that are "different than" those established by the federal government. It also prohibits laws and regulations "in addition to" those set forth in the FMIA. This fact is fatal to the petitioners' arguments.

Any Michigan provision that concerned the marking, labeling, packaging, or ingredient requirements of the meat involved in this case would necessarily have been "in addition to" the requirements of the FMIA and would have been preempted for that reason. This conclusion is independent of any federal statute or regulation concerning meat containing E. coli and does not depend upon the existence of federal action concerning such meat.

The fact that the FMIA prohibits any state regulation "in addition to" its own provisions demonstrates a fundamental error

in the petitioners' arguments. They have treated this case as one that involves only an actual conflict between federal and state law; and, having supposedly demonstrated that there is no conflict, they claim that preemption has not occurred.

There are two errors inherent in the petitioners' approach. First, there is an actual conflict because, prior to 1994, the federal refusal to label meat containing E. coli as adulterated was fully equivalent to an affirmative decision that such meat was not adulterated. Second, given the FMIA's prohibition against state provisions "in addition to" its own, no actual conflict between state and federal law was necessary for preemption to occur. Preemption took place because the FMIA specifically said it did, and that expression of Congressional will was more than sufficient to effect preemption in this case.

The preemptive effect of the FMIA on state law and regulations "in addition to" its own is also made clear by the decision in *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973), which struck down major portions of Michigan's Comminuted Meat Law.

Although certain portions of the Comminuted Meat Law conflicted directly with federal regulations, a number of its provisions did not do so. That fact notwithstanding, even the provisions that did not establish requirements different from federal regulations were found to be preempted.

For example, the federal regulations governing the ingredients in sausage did not establish a requirement for overall moisture or protein content (468 F.2d 76, 87). The Comminuted Meat Law did so, however. M.C.L. 289.582(a)(1); M.S.A. 12.964(2)(a)(1). (These provisions are now found in M.C.L. 289.582(1)(e); M.S.A. 12.964(2)(1)(e).)

Despite the absence of any direct conflict between the federal regulations and Michigan law, the portions of M.C.L.

289.582(a)(1); M.S.A. 12.964(2)(a)(1) establishing the standards for overall moisture and protein content were held to be preempted (468 F.2d 76, 85).

The same conclusion must be reached in this case. Even if the USDA had not taken the position that meat containing E. coli was unadulterated, a state law or regulation declaring such meat adulterated would necessarily have been preempted because the FMIA and the federal regulations based on it establish the only standards for determining whether such meat is, in fact, adulterated.

Although the petitioners' arguments concern only meat containing E. coli, those arguments obviously would apply just as well to any characteristic of meat that has not been regulated by the federal government. If the petitioners' arguments were correct, then a state could pass laws and enact regulations affecting any such characteristic simply because the federal authorities had not yet done so. Is such a conclusion possibly correct? Of course not. If a state passed such laws and regulations, they would necessarily be "in addition to" the standards imposed by the FMIA and would be preempted by reason of 21 U.S.C. § 678. Such laws and regulations would fare no better than the portions of Michigan's Comminuted Meat Law concerning overall moisture and protein content that were found to be preempted in *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973).

The petitioners' arguments completely overlook the fact that the FMIA prohibits state laws and regulations "in addition to" its own, and their petition contains no discussion at all of that prohibition. By failing to recognize that the FMIA has preemptive force by its own terms, the petitioners have missed one of the most important points in this case.

D. *The FMIA Was Intended by Congress to Be Completely Preemptive.*

In addition to the language of the FMIA itself, the case law interpreting it demonstrates that Congress intended the FMIA to have completely preemptive effect. This conclusion is clearly set forth in *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973). The decision in that case states in the most definite terms that the FMIA completely preempts state law within its sphere of operation.

> * * * Thus, by prohibiting a state's imposition of "marking, labeling ... or ingredient requirements" which are "in addition to or different than [those made by the Secretary]," Congress has "unmistakably ... ordained" that the Federal Act fixes the sole standards. * * *

468 F.2d 76, 84.

* * *

> Congressional debates are devoid of any discussion of Section 408 of the Act (21 U.S.C. § 678). However, in view of its unambiguous language, Section 408 reflects unequivocal legislative purpose to make the Federal Act preemptive.

468 F.2d 76, 84-85.

* * *

> * * * Nevertheless, in view of the clear and complete preemption ordained by Congress, this Court must enforce the Supremacy Clause and declare that the Federal Act preempts certain provisions of the Michigan law. * * *

468 F.2d 76, 85.

In this case, as in *Armour*, the FMIA established the "sole standards" and effected a "clear and complete preemption" of any Michigan law or regulation "in addition to, or different than" the FMIA's own provisions.

E. *Michigan Did Not Have Concurrent Jurisdiction to Make Laws and Regulations Concerning the Meat Involved in this Case.*

The petitioners err in claiming that 21 U.S.C. § 678 granted Michigan "concurrent jurisdiction" to regulate the meat involved in this case. Admittedly, 21 U.S.C. § 678 does say that " * * * any State may, consistent with the requirements under this chapter, exercise concurrent jurisdiction * * * for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded * * *." However, that provision did not apply to the meat involved in this case and could not possibly have conferred any jurisdiction on Michigan to regulate it.

The concurrent jurisdiction described in the quoted language applies only to "adulterated or misbranded" articles; and furthermore those terms must be given the meaning they have under federal, not state, law. This conclusion is clear from the decision in *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973) in which the Court said this about the language quoted above.

> The concurrent action of a state, permitted by this language, only applies to adulterated or misbranded articles. These words are necessarily used as defined in the act. * * * Permissible concurrent enforcement by a state under Section 678 would apply only to meat food products that satisfy this definition of misbranding [*i.e.*, the definition in 21 U.S.C. § 601(n)(7)]. In its concurrent enforcement a state would not be

> permitted to prevent the distribution in commerce of any article that "conforms" to the "definition and standard of identity or composition." Thus, Congress is ordaining uniform national ingredient requirements prescribed by the Secretary.

468 F.2d 76, 84.

At the time the meat involved in this case was sold and consumed, federal regulations did not classify meat containing E. coli bacteria as adulterated. Given that fact, Michigan had no concurrent jurisdiction to regulate the handling, inspection, labeling or sale of such meat because it was not adulterated as that term is used in the FMIA. At the times relevant to these cases, Michigan likewise had no power to prevent the distribution of meat containing E. coli bacteria because such meat was then in full compliance with the requirements imposed by the FMIA. The petitioners' arguments to the contrary are clearly incorrect.

F. *Given the Petitioners' Failure to Recognize that this Case Involves Preemption Arising From Congressional Mandate, Rather than from the Mere Conflict Between State and Federal Laws, Many of Their Arguments Are Irrelevant.*

Because the petitioners have misconstrued the reason why federal law has preemptive effect in these cases, many of their arguments are irrelevant to the issues actually involved in this appeal. It is, for example, immaterial whether the USDA's regulations are comprehensive or not (Petition, p. 19). The FMIA does not preempt Michigan law because of any particular characteristic of the regulations based on it. It preempts Michigan law because it is a federal statute and expressly says that it has preemptive effect.

It is likewise immaterial whether the petitioners have a remedy to replace the one being precluded by the federal statute

(Petition, p. 11). The absence of such an alternative remedy is relevant only when preemption arises because of a perceived conflict between state and federal law. Where a federal statute expressly provides for preemption, there can be no doubt about the effect of that statute; and the absence of some other remedy is, therefore, irrelevant.

As the petitioners themselves admit in their petition:

> * * * Where there is a specific preemption provision in a Federal statute, there is no need to consider whether preemption should be implied from the law or from Federal regulations. The question at that point is the proper interpretation of the express preemption provision. *Cipollone* v *Liggett Group, Inc*, 505 US 504; 112 SCt 2608; 120 LEd 2d 407, 423 (1992). As noted in *Cipollone* (*id*):
>
> > When Congress has considered the issue of preemption and has included in the enacted legislation a provision explicitly addressing that issue, and when the provision provides a "reliable indicium of congressional intent with respect to state authority," * * * "there is no need to infer congressional intent to preempt state law from the substantive provisions of the legislation" (citations omitted).

(Petition, p. 11).

Respondent Prevo's agrees fully with the quoted material from the petition. The situation present in this appeal is furthermore identical to the one described in that material, and thus it applies directly to this matter.

The FMIA contains a "specific preemption provision," and in light of that fact there is no question that it preempts state law. All of the petitioners' arguments about what might possibly be presumed or inferred from the nature of the regulations based on the FMIA, from the absence of some other remedy to replace the one precluded by the FMIA, or from the alleged failure of the federal government to regulate meat containing E. coli until 1994 are, therefore, irrelevant.

4. The Petitioners' Reliance on the Decisions in the Medtronic and Freightliner Cases Is Unfounded, and Those Cases Do Nothing to Support Their Position in This Matter.

In their petition the petitioners place significant reliance on the decisions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995). That reliance is unfounded. Neither of those decisions supports the petitioners' arguments in this matter.

Medtronic involved claims for personal injury allegedly caused by a defective pacemaker lead. The defendant manufacturer responded with an argument that the claim was preempted by federal law because 21 U.S.C. § 360k(a) provides that no state may establish or continue in effect, with respect to a device intended for human use, any requirement that is different from, or in addition to, any requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. § 301 *et seq.*

The Supreme Court disagreed and held that the petitioners' claim was not preempted. It did so for a number of reasons, not one of which applies to this case.

First and foremost, the Court's decision was based in large part on the fact that the Food and Drug Administration (FDA) has broad power to determine when and to what extent a statute

in the FDCA or a regulation based on such a statute has preemptive effect. The FDA, unlike many other agencies, has even passed regulations that place significant restrictions on the extent to which preemption occurs.

> The FDA regulations interpreting the scope of § 360k's preemptive effect support the Lohrs' view, and our interpretation of the pre-emption statute is substantially informed by those regulations. * * * In addition, Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect. Unlike the statute construed in *Cipollone*, for instance, pre-emption under the MDA [Medical Devices Act] does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal "requirement." * * *

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2255, 135 L. Ed. 2d 700, 722 (1996).

The regulations enacted by the FDA furthermore provide that preemption does not occur unless the FDA has enacted its own regulations speaking to the very same subject as the state law that is supposedly preempted or some unavoidable conflict between state and federal law is certain to result.

> The Lohrs' theory is supported by the FDA regulations, which provide that state requirements are preempted "only" when the FDA has established "specific counterpart regulations or * * * other specific requirements applicable to a particular device." 21 CFR § 808.1(d)(1995). * * *

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2257, 135 L. Ed. 2d 700, 723 (1996).

* * *

> * * * The regulations even go so far as to state that § 360k(a) generally "does not preempt a state or local requirement prohibiting the manufacturing or adulterated or misbranded devices" unless "such a prohibition has the effect of establishing a substantive requirement for a specific device. § 808.1(d)(6)(ii) * * *"

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2257, 135 L. Ed. 2d 700, 724 (1996).

* * *

> Although we do not believe that this statutory and regulatory language necessarily precludes "general" federal requirements from ever pre-empting state requirements, or "general" state requirements from ever being pre-empted, see Part VI, *infra*, it is impossible to ignore its overarching concern that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest. * * *

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2257, 135 L. Ed. 2d 700, 724 (1996).

This case involves nothing that is even close to the preemption doctrine that applies to the FDCA. The FMIA was intended by Congress to set the sole standards within its sphere of operation, and preemption occurs under the FMIA even if the federal government has not enacted laws or regulations concerning a particular question. *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981 (1973).

In *Medtronic* the Court also found preemption inapplicable because the petitioners were, in effect, seeking to use a state remedy to enforce a requirement that already existed under

federal law. In other words, the petitioners were looking to state law only for their remedy, not for the basis of their claim.

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, that the federal requirement. * * * The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Medtronic, Inc v. Lohr, 518 U.S. 470, __, 116 S. Ct. 2240, 2255, 135 L. Ed. 2d 700, 722 (1996).

In this case the situation is completely different. When the petitioners' claims arose in 1993, federal law did not consider meat containing E. coli bacteria adulterated; and thus the petitioners had no possible claim against respondent Prevo's under federal law. Indeed, the petitioners have even admitted that fact. See Part 4, *supra*.

The petitioners in this matter, unlike the petitioners in *Medtronic*, were not seeking a state remedy for violation of a federal requirement. They were likewise not seeking a state remedy for violation of a state requirement that was no broader than and essentially identical to one already existing under federal law.

To the contrary, they were seeking a state remedy for violation of a state requirement that was "in addition to" and "different than" the federal standard in effect at the time. Given that fact, the decision in *Medtronic*, based as it is on the fact that federal law established a requirement identical to the one under which the petitioners there sought to recover, does nothing to show that there is no preemption in this case.

The decision in *Medtronic* is obviously based on a statute and doctrine of preemption that are quite different from the ones involved in this case, and for that reason *Medtronic* simply does not apply to this matter. The petitioners' reliance on that decision is thus unfounded.

The decision in *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995) likewise fails to support the petitioners' arguments, and it does so for reasons similar to those affecting the decision in *Medtronic*.

Freightliner involved claims that certain tractor-trailers were negligently designed because they did not have antilock brake systems (ABS's). The manufacturer argued that these state law claims were preempted by the National Traffic and Motor Vehicle Safety Act of 1966 (the "Safety Act"), 15 U.S.C. § 1381 *et seq.* and its implementing regulations.

The Supreme Court disagreed and found no preemption. It did so for two reasons, neither of which exists in this case. First, the preemption provision in the Safety Act specifically provided that preemption occurred only when state and federal safety standards regulated the same aspect of performance of a vehicle or item of equipment and the standards were not identical.

> Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to

> continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard. * * *

15 U.S.C. § 1392(d).

Second, at the relevant times, previously enacted federal standards concerning the required stopping distances for trucks had been suspended by order of the Ninth Circuit Court of Appeals.

Given the language of the Safety Act allowing preemption only when a federal standard regulating the same subject matter was in effect and the suspension of the federal standard for stopping distances, the Supreme Court found the requirements of the statute had not been satisfied.

> Despite the fact that Standard 121 remains suspended, petitioners maintain that defendants' lawsuits are expressly pre-empted. We disagree. The Act's pre-emption clause applies only "[w]henever a Federal motor vehicle safety standard * * * is in effect" with respect to "the same aspect of performance" regulated by the a state standard. 15 U.S.C. § 1392(d) [15 U.S.C.S. § 1391(d)]. There is no express federal standard addressing stopping distances or vehicle stability for trucks or trailers. No NHTSA regulation currently establishes a "minimum standard for * * * motor vehicle equipment performance," § 1391(2), nor is any standard "stated in objective terms," § 1392(a). There is simply no minimum, objective standard stated at all. Therefore, States remain free to "establish, or to continue in effect,"

> their own safety standards concerning those "aspects of performance." § 1392(d).

Freightliner Corp. v. Myrick, 514 U.S. 280, 286 (1995).

The FMIA contains no provision like the one in the Safety Act that limits preemption to situations where state and federal standards speak to the same subject matter. The FMIA provides just the opposite, in fact, by providing that preemption occurs whenever any state law or regulation is "in addition to, or different than" the provisions of the Act itself. Thus, under the FMIA, a state law or regulation is preempted if it is simply "in addition to" the provisions of the Act, regardless of whether any portion of the FMIA regulates the same subject as the state enactment. The situation in *Freightliner* was quite different; and, therefore, the decision in that matter says nothing about whether preemption occurred in this case.

In addition, the decision of the USDA not to label meat containing E. coli bacteria adulterated was fully equivalent to an affirmative decision that such meat was not, in fact, adulterated; and thus preemption would occur in this case even if the FMIA contained the sort of restrictive preemption provision found in the Safety Act at issue in *Freightliner*.

The petitioners' arguments thus find no support in *Medtronic* or *Freightliner*. The petitioners' discussion of those decisions fails even to mention, much less take account of, the fact that each of them involved a preemption provision that is far more restrictive than the one involved in this case and that the decisions in those matters were direct (and necessary) consequences of the restrictive preemption provisions they were applying.

5. Neither the Petitioners' First Argument Nor Their Unsubstantiated Claim that They Alone Have Been Denied a Remedy for Exposure to Meat Containing E. Coli States a Valid Reason Why Their Claims Should Not Have Been Dismissed.

The petitioners misdirect their first argument. If the current regulatory procedures for meat products present problems (Prevo's denies that they do), the petitioners should direct their complaints at Congress, which placed an express preemption provision in the FMIA, and the USDA, which is allegedly not acting quickly enough in identifying new pathogens and labeling them as adulterants.

The petitioners' complaints and "parade of horribles" do not provide any reason, much less justification, for any court to refuse enforcement of an express preemption provision in a federal statute. Congress has clearly stated that the FMIA shall have preemptive effect, and that fact cannot be changed by any problems the petitioners claim they have identified in the inspection and labeling procedures the FMIA establishes.

The E. Coli problems associated with the Jack-in-the- Box hamburger chain have no relevance to this case, and the petitioners' discussion of them proves nothing. Jack-in-the-Box is a fast food retailer, and its liability in the various cases brought against it was based on improper cooking of the hamburgers it served. The express preemption provision of the FMIA is concerned with "marking, labeling, packaging, and ingredient requirements"; and it has nothing at all to do with cooking. Thus, the preemption provision of that act did not apply to Jack-in-the-Box in any way. The decision in this case thus has no effect whatsoever on the possible liability of a retailer selling hamburgers or other finished food products for claims based on improper cooking. It is misleading of the petitioner to suggest otherwise.

The petitioners' claim that they are the only victims of E. coli poisoning in the United States to be denied a tort remedy is both undemonstrated and irrelevant. It is undemonstrated because the petitioners have not cited one single case in which someone injured before 1994 by meat containing E. coli was allowed to recover from an entity covered by the preemption provision of the FMIA. In other words, the petitioners have failed to show that any other jurisdiction has refused to give preemptive effect to the FMIA for an E. coli injury that occurred before the USDA declared E. coli to be and adulterant in meat.

The petitioners' claim is irrelevant for at least two reasons. First, to the extent that it is based on claims asserted against fast food retailers such as Jack-in-the-Box for improper cooking, it proves nothing because the preemption provision of the FMIA does not apply to cooking. Second, if other states have failed to recognize the preemptive effect of the FMIA, they have clearly erred by doing so. Their errors certainly provided no valid reason why the courts of Michigan should have repeated their mistakes.

6. The Petitioner's Argument Based on What This Court Might Have Done in *Lewis v. Brunswick*, No. 97-288, Has No Merit.

The petitioners' final argument is based on a claim that this Court might have reversed the decision *Lewis v. Brunswick Corp.*, 197 F.3d 1494 (11th Cir. 1997) if the case had not been settled prior to the release of an opinion. That argument has no merit.

The opinion of petitioner's counsel about what this Court might have done in a case in which no decision was ever rendered is speculative and totally irrelevant to any question involved in this case.

Furthermore, even if the Court had modified the decision of the Eleventh Circuit Court of Appeals in *Lewis v. Brunswick*

Corp., 197 F.3d 1494 (11th Cir. 1997), its decision would have had little, if any, relevance to this matter because of the different express preemption provisions contained in the Federal Meat Inspection Act (FMIA) and the Federal Boating Safety Act (FBSA).

The petitioners also place reliance on the amicus curiae brief of the Solicitor General submitted to this Court in *Lewis*. That reliance is unfounded. The arguments set forth in that brief are clearly statute specific, and their reasoning could not possibly apply to the express preemption provision in the FMIA because it differs significantly from the preemption provision in the FBSA.

In addition, it is axiomatic that the law is stated by the courts, not by the Department of Justice, the Solicitor General, or anyone else who takes a position on a particular issue for undisclosed reasons that may well have no connection whatsoever with the merits of that issue. The petitioners' attempt to use the position taken by the Solicitor General in the *Lewis* case as "authority" for their position thus necessarily fails.

CONCLUSION

For the reasons set forth above, respondent, Prevo's Family Market, Inc., respectfully requests the Court to deny the petition for a writ of certiorari.

Respectfully submitted,

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